EXHIBIT A

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY
MDL NO. 2875

----------X

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION

THIS DOCUMENT RELATES TO:

All Actions

Case No. 1:19-md-02875-RBK-SAK

----------X

VIDEO DEPOSITION OF : RON NAJAFI
February 3, 2022
* * * * * *

TRANSCRIPT of the videotaped deposition of the above-named witness, called for Oral Examination in the above-entitled matter, said deposition being taken pursuant to Superior Court Rules of Civil Practice and Procedure, by and before MICHELLE L. DAWKINS, CSR, RPR, a Certified Court Reporter and Notary Public of the State of New Jersey, held REMOTELY VIA ZOOM on Thursday, February 3, 2022, commencing at 9:09 a.m. Pacific Standard Time.

APPEARANCES:

For the Plaintiffs:

KANNER & WHITELEY LLC
BY: LAYNE HILTON, ESQ.
DAVID STANOCH, ESQ.
CONLEE SCHELL WHITELEY, ESQ.
701 Camp Street
New Orleans, LA 70130
504.524.5777
l.hilton@kanner-law.com
d.stanoch@kanner-law.com
c.whiteley@kanner-law.com
LEVIN PAPANTONIO THOMAS MITCHELL RAFFERTY & PROCTOR P.A.
BY: DANIEL NIGH, ESQ.
316 South Baylen Street
Pensacola, FL 32502
850.435.7013
dnigh@levinlaw.com
LEVIN SEDRAN & BERMAN LLP
BY: CHARLES E. SCHAFFER, ESQ.
510 Walnut Street - Suite 500
Philadelphia, PA 19106
215.592.1500
cschaffer@lfsblaw.com

SLACK DAVIS SANGER LLP
BY: JOHN R. DAVIS, ESQ.
6001 Bold Ruler Way - Suite 100
Austin, TX 78746
866.531.2048
jdavis@slackdavis.com

APPEARANCES (Continued):
For the Defendants, Mylan Pharmaceuticals Inc., Mylan Laboratories Ltd., Mylan Inc., and Mylan N.V.:

PIETRAGALLO GORDON ALFANO BOSICK & RASPANTI, LLP
BY: CLEM TRISCHLER, ESQ.
FRANK STOY, ESQ.
JASON M. REEFER, ESQ.
One Oxford Centre
301 Grant Street - 38th Floor
Pittsburgh, PA 15219
412.263.4385
cct@pietragallo.com
fhs@pietragallo.com
jmr@pietragallo.com

For the Defendants, Aurobindo Pharma USA, Inc., Aurobindo Pharma Ltd., and Aurolife Pharma LLC:

MORGAN LEWIS & BOCKIUS LLP
BY: JOHN GISLESON, ESQ.
STEVEN HUNCHUCK, ESQ.
One Oxford Centre - 32nd Floor
Pittsburgh, PA 15219
412.560.7466
john.gisleson@morganlewis.com
steven.hunchuck@morganlewis.com

For the Defendants, Zhejiang Huahai Pharmaceutical Co., Ltd., Solco Healthcare U.S., LLC, and Prinston Pharmaceutical Inc.:

DUANE MORRIS LLP
BY: ALYSON WALKER LOTMAN, ESQ.
COLEEN HILL, ESQ.
30 S. 17th Street
Philadelphia PA 19103
215.979.1177
alotman@duanemorris.com
cwhill@duanemorris.com

APPEARANCES (Continued):
For the Defendant, Cygnet Pharmaceuticals, Inc.:

HINSHAW & CULBERTSON LLP
BY: GEOFFREY M. COAN, ESQ.
53 State Street - 27th Floor
Boston, MA 02109
617.213.7000
gcoan@hinshawlaw.com

For the Defendant, Camber Pharmaceuticals:

LEWIS BRISBOIS BISGAARD & SMITH LLP
BY: ASHER A. BLOCK, ESQ.
500 East Swedesford Road - Suite 270
Wayne, PA 19087
215.977.4066
asher.block@lewisbrisbois.com

For the Defendants, CVS Pharmacy Inc. and Rite Aid:

BARNES & THORNBERG
BY: KARA KAPKE, ESQ.
11 S. Meridian Street
317.231.6491
kkapke@btlaw.com

For the Defendant, Humana:

FALKENBERG IVES LLP
BY: MEGAN A. ZMICK, ESQ.
230 West Monroe - Suite 2220
Chicago, IL 60606
312.566.4801
maz@falkenbergives.com

APPEARANCES (Continued)
For the Defendants, Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical Industries Ltd., Actavis LLC, and Actavis Pharma, Inc.:

GREENBERG TRAURIG, LLP
BY: STEVEN M. HARKINS, ESQ.
VICTORIA LOCKARD, ESQ.
BRIAN RUBENSTEIN, ESQ.
Terminus 200
3333 Piedmont Road NE - Suite 2500
Atlanta, GA 30305
678.533.2312
harkinss@gtlaw.com
lockardv@gtlaw.com
rubensteinb@gtlaw.com
MARTIN, HARDING & MAZZOTTI
BY: ROSEMARIE RIDDELL BOGDAN, ESQ.
100 Park Avenue Center - 16th Floor
New York, NY 10017
518.724.2207
rosemarie.bogdan@1800law1010.com

WALSH PIZZI O'REILLY FALANGA LLP
BY: CHRISTINE GANNON, ESQ.
Three Gateway Center
100 Mulberry Street - 15th Floor
Newark, NJ 07102
973.757.1017
cgannon@walsh.law

For the Defendant, Albertson's LLC:

BUCHANAN, INGERSOLL & ROONEY P.C.
BY: CHRISTOPHER B. HENRY, ESQ.
Carillon Tower
227 W. Trade Street - Suite 600
Charlotte, NC 28202
704.444.3475
christopher.henry@bipc.com

A P P E A R A N C E S (Continued):
For the Defendant, McKesson Products:
NORTON ROSE FULBRIGHT U.S. LLP
BY: ELLIE NORRIS, ESQ.
2200 Ross Avenue - Suite 3600
Dallas, TX 75201
214.855.8135
ellie.norris@nortonrosefulbright.com

ALSO PRESENT: WILLIAM MILLER, Videographer
Veritext Legal Solutions

INDEX TO WITNESSES

PREMARKED EXHIBITS

THE VIDEOGRAPHER: Good morning. We are going on the record at 9:09 a.m. Pacific time on February 3, 2022. This is Media Unit 1 of the video recorded deposition of Ron Najafi, PhD in regards to the valsartan/losartan litigation which is found in United States District Court, district of New Jersey, NDL No. 2875. My name is William Miller from the firm Veritext Legal Solutions and I am the videographer. The court reporter is Michelle Dawkins from the firm Veritext Legal Solutions. All counsel is noted on the stenographic record. Will the court reporter please swear in the witness. You're on mute, Michelle.

THE COURT REPORTER: Sorry. Good morning. My name is Michelle Dawkins and I am the court reporter. The attorneys participating in this deposition acknowledge that I am not physically present in the deposition room and that I will be reporting this deposition remotely.

They further acknowledge that in lieu of an oath administered in person, I will administer the oath remotely. The parties and their counsel consent to this arrangement and waive any objections to this manner of reporting.

Please indicate your agreement by

Page 10

stating your name and your agreement on the record.
MR. TRISCHLER: Clem Trischler. So agreed on behalf of the defendants.
MR. NIGH: Daniel Nigh, agreed on behalf of the plaintiffs.
THE COURT REPORTER: Would the witness please state his full name.
THE WITNESS: My name is Ron Najafi.
THE COURT REPORTER: Mr. Najafi, would you please raise your right hand. Do you solemnly swear or affirm the testimony you will give at this deposition will be the truth, the whole truth and nothing but the truth?
THE WITNESS: Yes, I do.
THE COURT REPORTER: Thank you.
DIRECT EXAMINATION
BY MR. TRISCHLER:
Q Sir, let me start by saying good morning. I think it's morning where you're located, so I'll say good morning to you.
A Good morning to you.
Q Thank you. My name is Clem Trischler. I am an attorney. I represent one of many defendants in litigation that's pending in the United States District Court for the district of New

Page 11

Jersey involving valsartan.
I understand that you've been identified and designated an expert witness in this litigation; is that correct?
A That's correct.
Q I'd like to maybe start today by covering some basic concepts and see if we can get an agreement on a few basic points. Okay?
A Okay.
Q Number one, it is an established fact that all drug products contain impurities, agreed?
A Yes, they do.
Q A drug or a drug substance is not considered misbranded simply because it contains impurities, true?
MR. NIGH: Form objection. Outside the scope.
A A drug product contains impurities that are harmless and they could also contain impurities that could be extremely hazardous.
Q That wasn't my question, sir. See if you can listen to my question and give me an answer to my question, please.
A drug product is not considered misbranded simply because it contains impurities; isn't that

Page 12

true?
MR. NIGH: Form objection. Outside the scope.
A A drug, as I mentioned to you, Mr. Trischler, drug product contains impurities that could be harmless or could be hazardous.
Q Is a drug product considered misbranded under federal law merely because it contains impurities?
MR. NIGH: Form objection. Outside the scope.
A A drug product, as I mentioned, contains impurities that could be harmless or could be hazardous and they could be misbranded because of the hazardous nature of the impurities.
Q If a drug product contains impurities that are not harmful to public health, are those drug products considered to be misbranded?
A No.
MR. NIGH: Form objection. Outside the scope.
Q If a drug substance -- every drug substance ever made in America has impurities, correct?
A Every drug product that is made in

Page 13

America or anywhere on the planet could contain impurities that are harmless or could be hazardous.
Q I didn't ask you that question, sir. I said, isn't it a fact that every drug product ever made in America or on the planet does contain some impurities?
MR. NIGH: He answered the question. He answered the question previously and it's outside the scope.
MR. TRISCHLER: It's not an appropriate objection. It's not an appropriate instruction, if that's what it was. My question stands -- excuse me. And I'd like an answer.
MR. NIGH: Objection. Asked and answered.
MR. TRISCHLER: I don't know how you know that, since I haven't asked it yet, but let me try again.
Q Every drug product ever made in the United States made for sale in the United States of America contains some impurities. Can we agree on that?
MR. NIGH: Objection. Asked and answered.
A I already responded to that question,

Page 14

sir.
Q I'm asking it again, then, sir. I ask you to answer my question, sir.
A Sir, I will give you the same answer.
Q What is the answer to my question?
A I just gave you the answer to your question. Every drug product or every drug substance that's produced on the planet contains harmless and harmful impurities.
Q If the mere presence of an impurity rendered a drug product adulterated and misbranded, then virtually pharmaceutical produced today would be deemed misbranded and adulterated, do you agree?
MR. NIGH: Form objection. Outside the scope.
A I did not say that. I said --
Q I didn't -- sir, let me stop you. I didn't ask you what you said. I asked you a question. Do you understand that this is a question and answer session and I am permitted to ask you questions and you're required to give me responsive answers to those questions; is that a concept you understand?
MR. NIGH: Mr. Trischler, you just now interrupted the witness in the middle of his answer.

Page 15

It wasn't completed.
Q Do you understand that I am entitled to answers to my questions, sir?
MR. NIGH: Do you understand not to interrupt the witness when he's answering your question?
MR. TRISCHLER: I'm not going to get into a colloquy with you. I'm talking to the witness. Do you understand --
MR. NIGH: Well, please don't interrupt the witness in the middle of his question -- I mean, in the middle of his answer.
Q Do you understand that I'm entitled to responsive answers to my question, sir?
A Clem, every drug product or drug substance that's produced on the planet contains harmless or harmful impurities. They could be misbranded if it contains extremely harmful impurities and they could not be misbranded if they are not harmful.
Q So then you would agree with me that the mere presence of some impurity does not render a drug product misbranded or adulterated, right?
MR. NIGH: Scope.
A I already responded to your question.

Page 16

I think you should -- I think it's -- the answer is clear.
Q Do you agree that the mere presence of an impurity does not render a drug adulterated or misbranded?
MR. NIGH: Objection. Scope.
A I responded to your question.
Q Sir, I am entitled to an answer to the question. I don't know if there was an internet issue. If there is was an answer, I didn't hear it.
A There is no internet issues.
Q I said I didn't hear. If there was an answer, I did not hear it.
MR. NIGH: Was there an answer to the last question, Michelle?
A I already answered it.
Q I'm not talking to you, sir.
A Let's move on to the next question.
(The previous testimony as requested was read by the reporter.)
MR. TRISCHLER: Okay. Thank you.
Q It's not clear to me, so I would like an answer, please. Is it your testimony that the mere presence of an impurity renders a drug misbranded or adulterated; yes or no?

Page 17

MR. NIGH: Again, it's outside the scope.
A I already responded to your question. Just look at the record. Go back to the records and you'll see my answer.
Q So are you refusing to answer my question, sir?
A I already responded to your question.
Q No, you didn't. No you didn't. I asked a different question, sir. This is going to be a long day or else we're going to come back and I'm going to get fees, because Magistrate Judge Menaski has talked about obstructionist witnesses like this. So if you don't want to answer the question, that's fine. We'll halt the deposition, I'll get fees for it, and we'll come back here again.
The question is pretty simple. Is it your position that the mere presence of an impurity renders a drug adulterated or misbranded; yes or no?
MR. NIGH: Object to the colloquy given to the witness. Disagree, but I will ask the witness to answer this question again.
A Again, this is not a "yes" or "no" answer, because mere presence of an impurity, if

it's safe impurity if it's determined safe, then it's not misbranded, but if it's an unsafe impurity then, yes, it is misbranded.

Q Does FDA require the supplier of an active pharmaceutical ingredient used in generic drug to use the same synthetic process used by the RLB holder?

MR. NIGH: Form objection.

A The FDA does not require the generic manufacturers to use exact procedure of the branded drug.

Q When you say "exact procedure," my question as are they required to use the same synthetic process for developing and producing API. The answer is no, correct?

MR. NIGH: Form objection. Outside the scope.

A Mr. Trischler, am I pronouncing your name right?

Q Close enough, sir.

A Mr. Trischler, FDA does not require a generic manufacturer to use exact chemical procedure as the brand to synthesize the generic drug.

Q And because the synthetic process used by an RLD holder in a generic manufacturer may be

different, it's not uncommon or unexpected that the API used in an ANDA will have a different impurity profile than the reference listed drug, is it?

MR. NIGH: Form objection. Outside the scope.

A It is entirely possible that the impurity profile of the generic drug may be different.

Q In fact, there's absolutely no requirement anywhere in the FDA regulations that mandate that an RLD match or mirror the impurity profile of the generic alternative, is there?

A The FDA does not require that the generic drug manufacturer to match every impurity of the branded drug.

However, they do require that the impurity is to be determined safe. They do require that a generic drug does sufficient due diligence to determine the synthetic path is safe.

Q A generic manufacturer can establish and satisfy FDA requirements for bio equivalents even where the impurity profiles between the RLD and the generic equivalent product are different, correct?

A Could you repeat your question.

Q Yes. A generic drug manufacturer can establish and satisfy FDA requirements for bio equivalents even where the impurity profiles between the RLD and generic equivalent product are different.

A The generic drugs have to establish bio equivalence when they make a generic drug.

Q Right. And you can --

A A bio equivalence does not refer to, you know, impurity profile.

Q I understand. My question was bio equivalence can be established in having impurity profiles that match as between the reference listed drug and the generic applicant, correct?

A No, I didn't say that.

Q Then answer the question.

A Repeat your question please.

Q Sure. I said that a generic drug manufacturer can meet FDA requirements for bio equivalence without having an impurity profile that matches the impurity profile of the reference listed drug.

A The generic manufacturer can establish bio equivalence or a synthetic process irrespective of whether they have -- what kind of impurities they

have. They could have harmful impurities, they could have harmless impurities, and they can still establish bio equivalence, but that's irrespective of what kind of impurities they have.

Q Does the Food, Drug, and Cosmetic Act contain a definition of an adulterated product?

MR. NIGH: Form. Outside the scope.

A To me, adulterated products are products that have been contaminated.

Q Well, I appreciate your definition, but I'm really not interested in it. My question was, does the Food, Drug, and Cosmetic Act contain a definition of what constitutes adulterated product?

A Yes, they do.

MR. NIGH: Hold on. Hold on. Object to the colloquy. It's inappropriate. You can answer.

A Adulterated products are products that are mislabeled. They don't have proper label and they could have toxic impurity in it, either intentionally or inadvertently, and they could be called adulterated.

Q Have you ever read the definition of an adulterated drug product under the Food, Drug, and Cosmetic Act?

Page 22

A Yes, I have.
Q Are you familiar with the definition under Section 351 of the Food, Drug, and Cosmetic Act?
A I haven't looked at it exactly today, but I am familiar with that.
Q Section 351 defined an adulterated drug as one where its strength differs from or its quality impurity fall below the standards set forth in the compendium.
A I agree with that.
MR. NIGH: Hold on. Was there a question?
MR. TRISCHLER: There was.
A You just read the definition.
Q Right. And you would agree with that definition, right?
MR. NIGH: Form objection. Outside the scope.
Q You agree with that definition, sir?
A If you're reading it from the regs, yes.
Q And where there is a USP monograph, any article marketed in the United States must meet the requirements and specifications of the

Page 23

monograph. Agreed?
A Would you repeat your question?
Q Sure. Where there is a USP monograph, any drug product marketed in the United States must meet the requirements and specifications of that monograph?
A USP drug is the minimum requirement that is required, absolute minimum. Manufacturers are required to go above and beyond those requirements.
Q Are they required to meet -- where a monograph exists and applies, are manufacturers required to meet their specifications of the monograph?
A You spoke too fast. You got cut out. Could you repeat?
Q I'll try. Where there is a USP monograph that applies to a drug product are manufacturers required to meet those specifications and criteria in the monograph?
MR. NIGH: Objection. Asked and answered.
A I answered that question already. USP monograph is the minimum standards and manufacturers are required to go above and beyond that.

Page 24

Q Can you cite me an authority for the proposition that you just stated, that the USP monograph is a minimum standard? Where is that specified anywhere in the public literature?
A I can't put my fingers on it right now, but I can look it up for you and show you.
Q Well, we'll take multiple breaks during this day and so I'd like you to find me --
A I will.
Q Let me finish, please. Can I finish, please?
A Absolutely.
Q Sir, this is really difficult if we talk over one another. I'll do my best not to talk over you, but please let me finish my statement and my question.
I'd like you to cite for me the authority for that novel proposition that you just offered, because I've not seen it.
A I will.
MR. NIGH: Hold on. Hold on. Hold on. Form objection and now I would object to whatever exercise there is that is supposed to do something during the breaks while he's trying to take restroom breaks. We are going far outside the

Page 25

scope of his opinion and he has authority in his expert report if you want to read his certification.
A Sir, can I respond to that question? I think that I can refer you to USP's website and under, basically, overview, USP monograph basically articulates that there is a minimum quality standards and the companies have to go above and beyond that.
Q So I will find that on USP website?
A You should able to find that on USP website, usp.com. Go to about USP and you should be able to find that.
Q Will I find that requirement posted anywhere else?
A I don't know. I'm sure there are. If you Google it, you will find it.
Q Is there any requirement anywhere in the USP mandating that a generic equivalent product match or mirror the impurity profile of the RLD?
MR. NIGH: Form objection.
A There is the regs -- first of all, USP is not a regulatory body. USP is an independent company. The regs are clear. There is the concept of sameness, chemical equivalents, active equivalents, impurity equivalents, and there is the

Page 26

concept of bio equivalents, therapeutic equivalents. I can't comment on a lot of those things because I am not a physician, but those are all spelled out in the regs and you can look that up.

Q Where is the requirement for what you call chemical equivalent, where is that term used in the Food, Drug, and Cosmetic Act or the regulations of the FDA?

A It's cited in my report, sir.

Q No, it's not. You don't provide any citation for what constitutes chemical equivalents in your report.

MR. NIGH: Objection. Hold on. I don't know if that was a question.

A I responded to your question.

Q Show me in your report --

A Look at my report.

Q Show me in your report where there is a regulatory definition of what you just called chemical equivalence. You can look at your -- take your time. Look at your report and show me where there is a definition of chemical equivalence either in Food, Drug, and Cosmetic Act or regulations in the FDA or in any guidance in the FDA, for that matter.

Page 27

A Okay. Hang on one second. I've got to get the report from my desk.

THE VIDEOGRAPHER: Would you like to go off the video record or would you like to stay on?

MR. TRISCHLER: I don't care.

A Okay. I'm back. Sorry. I put this on my computer. Basically, the generic drug manufacturers have an ongoing federal duty of sameness in their product and their reference is reference No. 2. What that refers to is that the identity of the active ingredients need to be exactly the same. The chemical synthesis of the actual ingredients need to be the same. And also, this refers to the impurities that are present need to be impurities that are either established by the brand, established by the USP or impurities that are established by the generic manufacturers; and those impurities, if the generic is using exactly the brand chemical procedure, if they are using the same recipe with the same, basically, various ingredients that they're using; different intermediates, different reagents, if they are using the same, then they should expect to have the same chemical impurities.

Page 28

If they are modifying the chemical procedure, in which case in the case of your clients they are modifying their brand's chemical procedure, then they should expect a different chemical impurities. And because they are modifying those chemical procedures and the reagents, then they have an obligation to identify those impurities and determine that they are not genotoxic.

It's a very long winded question to my, basically, one paragraph. It's No. 18 in my expert report.

MR. TRISCHLER: Object and move to strike as nonresponsive.

Q Do you remember what they question was?

MR. NIGH: Hold on. This has already been discussed that it's inappropriate during the deposition. It's already been ruled on to object as nonresponsive. The colloquies that you're giving, Mr. Trischler, have been ruled on previously as inappropriate.

You've also threatened sanctions. That's also been ruled on as being inappropriate. These are all the things that the defendants argued that Mr. Slater was doing that was inappropriate and

Page 29

now you're doing it yourself after Judge Menaski ruled that all these issues are inappropriate. We've got to put some brakes on this.

MR. TRISCHLER: Are you done with your speech, Daniel? I just asked him.

MR. NIGH: No, no, no, no. You can't ask him --

MR. TRISCHLER: All I am asking is if he remember --

MR. NIGH: You can't move to strike. It's inappropriate, and the combativeness with this witness is completely inappropriate. It's not just the speech. We can have a conversation with the judge if we need to.

MR. TRISCHLER: Are you done?

MR. NIGH: No, I'm not done. I don't think you're recognizing it. You're doing so many inappropriate things. We have to not do this. You can't badger this witness.

MR. TRISCHLER: If you need to call the judge, go ahead. I welcome it.

MR. NIGH: Okay.

MR. TRISCHLER: I welcome it.

MR. NIGH: Are you going to keep doing the things you're doing?

MR. TRISCHLER: Because I would love the judge to read this transcript.

MR. NIGH: Do you have every intention to keep threatening for sanctions? Do you have every intention to keep moving to strike as nonresponsive, because if you do, then we might as well call the judge now, because he's already ruled that that's inappropriate.

MR. TRISCHLER: I have already intention of asking relevant questions and I'm hoping to get some responsive answers to those questions.

MR. NIGH: Okay. Well, I hope that you stop moving to strike as nonresponsive and threatening sanctions.

MR. TRISCHLER: If you want to call the judge, I'd welcome it, because I would love for him to have the opportunity to read this transcript.

A Please repeat your question.

Q You used the term "chemical equivalents" and suggested that generic manufacturers have an obligation to establish chemical equivalents and my question to you, sir, was where in the Food, Drug, and Cosmetic Act or the regulations of the FDA is the term "chemical

equivalents" anywhere defined and where would that requirement be established? That was what led you to look at your report. That's the question that I'm looking for an answer to.

A Okay. Let me go back to my report again, okay. So I'm going to read back from my report, okay. Generic drug manufacturers have an ongoing federal duty of sameness in their product, reference No. 2. The generic manufacturers must demonstrate that their active ingredients are -- and have identical strength quality, purity -- I underlined that purity -- and potency and were applicable other characteristics as the reference listed drug.

(Clarification requested by the reporter.)

A I will repeat. Generic drug manufacturers have an ongoing federal duty of sameness, meaning equivalence, in their products. The generic manufacturers must demonstrate that their active ingredients -- in this case active compounds, the compound that's responsible for its therapeutic potential -- are the same as reference listed drug. "Same" here, Mr. Trischler, means identical; identical chemical structure, identical

molecular weight, identical to every sense of chemical sense. They should have same strength, same quality, purity.

Purity here refers to the chemical purity of the drug and the impurity profiles of those drugs; and both potency. And potency is really a function of, you know, excipients and what excipients it's in and whether it's going to be released properly.

So you get into a -- you know, I could talk about this for a couple hours, but that's what that is. And I'm referencing No. 2, No. 3, No. 4, these are basically the regs that are there.

And the regs, as you well know, are vague enough and that can be -- you know, they are really the minimum standards. You know there is a concept that they say CGMP. C talks about current good manufacturing practices and "current" means the highest technology, technologies, of today; and the generic are responsible to living up to that standard of the latest standards.

I hope -- that was a long answer to your question. I hope that I answered it.

Q It was long. It was not an answer to the question, but I'll ask it again.

A Well, you know, that's my answer. If

you want, I can repeat the same thing that I just gave you.

Q If you could stop talking for a minute, I'll try to ask another question. What you read from was paragraph 18 of your report, correct?

A Correct.

Q In paragraph 18 the words "chemical equivalent" never appear, do they?

A Chemical equivalents --

Q Do the words chemical equivalent appear?

MR. NIGH: No, no, no, no, no, no, no, no.

Mr. Trischler, he was clearly not finished with his answer there. No, no, no. That is completely inappropriate. You can finish your answer, Dr. Najafi.

MR. TRISCHLER: He has to answer it first and then he can --

MR. NIGH: No, he does not. Let him answer the question. Let him answer the question. That's completely inappropriate.

MR. TRISCHLER: Now you're saying he can't answer the question?

MR. NIGH: You're interrupting the

Page 34

witness over and over and over again. He was not done and he was starting to answer your question. He got two words out and you interrupted him; two words out. The video record is very clear on this.

MR. TRISCHLER: You just said he doesn't have to answer the question. That's what you just said.

A No, I did not say he doesn't have to answer the question. I said he doesn't have to answer it in the way that you want him to answer it at the very beginning of the answer.

MR. TRISCHLER: Let's try it again.

MR. NIGH: How about you ask the question and don't interrupt him, please.

MR. TRISCHLER: Let's try again.

MR. NIGH: That's pretty inappropriate.

BY MR. TRISCHLER:

Q Do the words "chemically equivalent" appear anywhere in paragraph 18 of your report?

A The word "equivalence" doesn't need to appear in No. 18. Sameness is chemical equivalence.

Q Is there a definition of chemical equivalence in the Food, Drug, and Cosmetic Act?

A I don't know.

Page 35

Q Is there a definition of chemical equivalence in the regulations established by the FDA?

A I don't know.

Q Is there a -- you used the term "impurity equivalence." Is there a definition of impurity equivalence under the Food, Drug, and Cosmetic Act?

A The definition I just read, it's the -- regs are clear the active ingredients need to be the same. They need to be identical. The quality, purity; you know, the identity of the drug needs to be identical; potency, those are what chemical equivalence is referring to. Perhaps I'm not giving you the answer you like to hear, but that's the answer.

Q Is impurity equivalence a defined term under the Food, Drug, and Cosmetic Act?

A I gave you my answer, you know. You have to have -- you know, the purity profile need to have -- you either are following the brand procedure and recipe, then you're going to end up with the same impurity profile. If you're not following the brand's procedure, you're going to end up with different impurity profile. Those impurities can be

Page 36

safe, can be harmful.

Q Sir, I didn't ask you any of that. All I simply asked you is you used the term "impurity equivalence" earlier in your testimony and my question is the term impurity equivalence a defined term under the Food, Drug, and Cosmetic Act?

A I have to -- you know, I can look that up during the break and get back to you.

Q Do you know if the term impurity equivalence is defined in the FDA regulations or FDA guidance?

A Purity profile is the same. You know, basically you have to have -- you know, I responded to the question. You're either following the brand's recipe and you get the same purity/impurity profile and the same purity or you're not following brand's procedure.

If you're not following brand's procedure you're going to get a different impurity profile and those impurity profiles could have genotoxic compound in it and it could be non-genotoxic compound in it.

Q Not my question again, sir. My question was simply do you know whether the term that you used "impurity equivalence" is a term that is defined in any FDA guidance document or FDA

Page 37

regulations?

A It may --

MR. NIGH: Hold on. Form objection. Just give a little bit of time between his question and your answer, because I may have an objection, form objection. You can answer.

A It may or may not.

Q Does FDA ever establish a requirement that a drug manufacturer identify all impurities in its drug label?

A Would you repeat your question?

Q Is there any FDA requirement for a drug manufacturer to identify all impurities in its drug label?

A There is a requirement that the manufacturers identify all impurities that are greater than certain percentage, and also there is a requirement that the manufacturers identify any potential genotoxic impurities. And typically those are considered impurities of concern because of their genotoxicity and those impurities are predetermined or pre -- sort of predicted by the expert chemist at the manufacturers based on certain ingredients and based on certain chemical structures that may be used.

Page 38

Q You know what I mean by labeling?
A Please define it.
Q Labeling is a defined term under the Food, Drug, and Cosmetic Act. Are you familiar with the FDA definition of the term?
A Why don't you give me the FDA definition.
Q I don't have it in front of me, but for purposes of today I'm talking about the full prescribing information provided to prescribers and patients when their drug is dispensed. Okay?
A Right.
Q Do manufacturers identify impurities in their FDA-approved labeling?
A They do. Manufacturers do identify impurities --
Q Okay.
A -- in their drug.
Q As part of your work in this case, did you review the Diovan labeling?
A No, I haven't.
Q Have you reviewed the Exforge labeling?
A No, I haven't.
Q I think I sent some potential exhibits

Page 39

ahead of time to the court reporter that we premarked. I think I premarked Exhibit 13 as a Diovan label.
A I was told -- I got a piece of mail here. I was told not to open it until you guys instruct me. Is that the one you want me to open it?
Q No, I didn't ask you to open anything.
A Okay. You want me to open it?
Q No. I have no idea what you're talking about. I didn't ask you to do anything.
MS. HILTON: Just for the record, Clem, this was something that John Giselson and the Aurobindo counsel had sent to Dr. Najafi and instructed him not to open it. So Dr. Najafi, I think, continue to keep that box unopened until Mr. Giselson and the lawyers for Aurobindo question you.
BY MR. TRISCHLER:
Q What we marked as Exhibit 13 is a copy of the FDA approved labeling for Diovan.
A Okay.
Q Have you ever seen this before, sir?
A Could you make it bigger?
THE VIDEOGRAPHER: Sir, we just lost

Page 40

your video feed.
MR. NIGH: Is this document going to also be disclosed, because he can look at the full label and I don't see it here yet in the share file.
MR. TRISCHLER: Frank -- hold on a second. I'm talking to Frank Stoy from my office who I also think is listening in. Frank, why don't you put in the chat all the things that we premarked.
A I can't see this. I need to print this. So if you could email it to me, Daniel or Rosemarie, that would be great. I can print it so I can look at it. I can't read it.
MR. STOY: I could try to draw up these documents in the chat as we use it. There is also a share file link that I think Layne just put in the chat where, Dr. Najafi, you should be able to download the exhibits as they're marked.
THE WITNESS: Great.
BY MR. TRISCHLER:
Q So you can't see this, is that what you're telling me?
A I can't see it, no. I have a -- it's very small on my screen.
Q Well, then I guess --

Page 41

A What are you referring to?
Q Well, I guess -- hold on. I guess we need to take a break until you can see it.
THE VIDEOGRAPHER: Going off the record, yes?
MR. TRISCHLER: Yes.
THE VIDEOGRAPHER: The time is 9:58. This concludes Media 1.
(A recess was taken.)
(After the recess the following occurred:)
THE VIDEOGRAPHER: The time is now 10:14. We are back on the video record. This begins Media 2. And counsel, would you like me to put the document that was on the screen up again?
MR. TRISCHLER: Yes, please.
BY MR. TRISCHLER:
Q Doctor, earlier we had talked about the definition of "adulterated" under the Food, Drug and Cosmetic Act. Would you agree with me that the term "misbranded" is also defined under the statute?
MR. NIGH: Objection. Scope.
A Would you repeat your question?
Q Is the term "misbranded" defined in the Food, Drug, and Cosmetic Act?

Page 42

MR. NIGH: Objection to form.
A Yes, I believe it is defined.
Q And under the Food, Drug, and Cosmetic Act a drug is deemed misbranded when its labeling proves to be false or misleading. Can we agree on that definition?
MR. NIGH: Objection. Scope.
A I agree that a misbranded drug contains something that shouldn't be there.
Q Is that your definition or are you suggesting that's the definition provided in the Food, Drug, and Cosmetic Act?
MR. NIGH: Objection. Form.
A A misbranded drug is a drug that has false or misleading label.
Q Okay. Thank you. So now we are looking at the labeling for Diovan. I have marked it as Exhibit 13. Are you now able to see it?
A Yes. I have it on my second monitor here so I can actually see it. I am going to be looking at my own version, but I have it. I am looking at the same area.
Q All right. And can you go through this -- the label that we marked as Exhibit No. 13 and tell me where Novartis discloses the impurities

Page 43

in its Diovan product?
A Okay. Let me look.
MR. NIGH: Objection. Scope.
A So Novartis does not mention this particular genotoxic impurities, because their product didn't have any.
Q That wasn't my question. My question was where do they list any impurities.
MR. NIGH: Form objection. Scope.
A This is not the place where they would list their impurities.
Q Is there any requirement that impurities -- that a drug manufacturer list impurities in its label, FDA labeling?
MR. NIGH: Objection. Scope.
A I don't think there is any requirement, per se, to list it. You know, if you're looking at this label, you know, the only thing you see is the active compound.
Q And that's my question, sir. Does any drug manufacturer list or identify impurities in its labeling?
MR. NIGH: Objection. Scope.
A I don't believe they do, but they need to file it with the FDA. They need to let FDA know.

Page 44

They need to disclose it on their batch record. They need to identify it, all their degradation products, and disclose it to the FDA in their filing.
Q In their -- sorry. I thought you were finished. Well, that's true in part, but isn't it also true that all -- that there is an allowance for unknown and unidentified impurities in every drug product made and sold in America?
MR. NIGH: Was that a question?
MR. TRISCHLER: Yes, sir.
MR. NIGH: Objection. Scope.
A What was your question?
Q I said isn't it true that there is an allowance for unknown impurities in every drug product?
MR. NIGH: Objection. Scope.
A There is an allowance for unknown impurities for every drug, provided they are not genotoxic.
Q And prior to June of 2018, can we agree that there was no requirement established by the FDA or specified in USP for nitrosamine-specific testing?
MR. NIGH: Objection. Scope.

Page 45

Q Are you referring to particular valsartan drug?
A No, I'm talking about any drug. I said prior to June of 20-- 18, are you aware of any requirement that was established by the FDA or specified in USP that required nitrosamine-specific impurity testing.
MR. NIGH: Objection. Scope.
A So my answer is genotoxic compounds need to be identified per the ICH guideline M7, and I refer you to that. They need to be identified and they need to be reported and they need to be controlled and managed and, you know, the whole nine yards. And yes, they would have to be -- they would have to be measured and by various instrumentation: GC, GCMS, LCMS, they need to know the amount; and there was a limit on the amount allowable for various impurities genotoxic impurities, I should say.
UNIDENTIFIED SPEAKER: Excuse me, counsel. Are you in need of another court reporter or are you all set, Michelle? I was just told to join the meeting.
(Off the record.)
Q Do you know what the acceptance

Page 46

criteria was for impurities under the valsartan USP monograph in the summer of 2018?
MR. NIGH: Objection. Form.
Q The acceptance criteria was to produce the active compound and have impurities that are safe, that are inert and have a safe drug. That was the requirement, and there were impurities that were listed that could potentially be formed and those impurities are typically impurities that the brand discloses to the USP or USP also, you know, acquires it through their own research.
MR. TRISCHLER: Can you put up what was premarked as Exhibit 17, please.
A Okay.
Q Have you seen this document before, sir?
A Hang on a second. Let me -- this is you is -- yes I have.
Q What is it?
A It's a USP, you know, monograph for the -- basically, limits of different impurities and different -- you know, the acceptance criteria from USP's point of view.
Q And what's the acceptance criteria for impurities under the USP standards as set forth in

Page 47

Exhibit 17?
MR. NIGH: Objection. Scope.
A The acceptance criteria is to have, you know, basically each total -- each individual impurities not basically greater than .2 percent or not important .2 or .4, various impurities that are listed, and that would be the accepted criteria.
Q If you go to the next page of Exhibit 17, in particular Table 1, it lists the specification and acceptance criteria for unknown impurities is 0.1 percent, correct?
MR. NIGH: Objection. Scope.
A Let me. Are you -- okay. Thank you for making it bigger. So, yeah. As you can see from this impurity profile, there is no genotoxic impurity mentioned here.
Q I didn't ask you that, sir. I said, what's the acceptance -- was the criteria in the USP monograph for unknown impurities 0.1 percent. That's the only question I asked.
MR. NIGH: Form objection. His answer was responsive and I object to the colloquy. You could answer.
A The acceptance criteria presupposes that the compound in question has no genotoxic

Page 48

compound such as NDMA or NDEA, presupposes.
Q Where does it say that in the USP monograph?
A You don't see that on the screen. If it was part of the impurity profile, it would have been mentioned. Since it's not, it means it shouldn't have any.
Q Today in 2021 what does the USP for valsartan provide as to the impurity acceptance criteria?
MR. NIGH: Objection. Scope.
A I haven't looked at the latest -- I don't have access to that document but, you know, it presupposes there is no genotoxic compound in valsartan.
Q I'm puzzled by that, sir. Where is it written anywhere in regulations, guidance or USP acceptance criteria that these numbers presuppose no genotoxic impurities; does anyone say that other than Ron Najafi?
MR. NIGH: Object to the colloquy and object to scope.
MR. TRISCHLER: There was no colloquy. That was a question.
MR. NIGH: No, but beginning part of

Page 49

that question started out with, "I'm puzzled." That is a colloquy.
Q So this -- I will ask it again, sir. This idea that these acceptance criteria presuppose that there is no genotoxic impurities, where is that coming from?
MR. NIGH: Objection.
Q Where --
MR. NIGH: Form objection.
Q Where is that?
MR. NIGH: Sorry. Scope.
A I refer you to USP website and specifically there is a specific mention that for impurities known that are suspected carcinogen that are toxic, that are genotoxic, a quantitation and detection limit shall be established. This is USP. It is ICH guideline, ICH M7. It's FDA. You know, if you want me, I can specifically cite you page and the language during the break.
Q We don't have to. I would like that, but we don't have to do it right now, because during the last break I did some homework and I would ask you to take a look at Exhibit 27. This is the USP website you were telling me about, right?
A Right.

Page 50

MR. NIGH: Objection to the colloquy.
Q And you said this is the site where I can go to where there is going to be a statement and public pronouncement that the USP specifications are minimum standards, so look at Exhibit 27 and tell me where it says that, sir.
MR. NIGH: Form objection. Outside the scope. Mischaracterizes his testimony. You can answer.
A I am not sure what you found on USP website, if you found the right page, but I will point that to you later.
Q I'm asking you to take a look at Exhibit 27 and tell me if there is anything on Exhibit 27 that suggests that the USP monographs specifications are minimum standards.
A So, specifically monograph articulates the quality expectation for medicines, including for its identity, strength and performance. They are also described a test to validate that in medicine that its ingredients meet these criteria and basically, I would have to do my own search to show you that specific language. I'm not sure if you have it in the documents you gave to me.
Q Exhibit 27 is a multipage document.

Page 51

Do you want to look at the whole thing and see if there's anything in there to suggest that USP requirements are minimum standards?
A If you give me a second, I will look it up for you.
Q Sure. Let's go off the record.
A Let's go off line.
MR. NIGH: Hold on. What are you looking up at this point, Dr. Najafi, the exhibit? You're looking at the exhibit or you're looking it up online?
THE WITNESS: No. I want to go online and look up something for him.
THE VIDEOGRAPHER: Are we all okay to go off the record?
MR. TRISCHLER: Yes.
MR. NIGH: No. Do you want him to go online and look this up for you, Mr. Trischler?
MR. TRISCHLER: The witness said he wants to, so let's go off the record and we will come back when he's ready.
THE VIDEOGRAPHER: The time is 10:32. We are going off the video record.
(A recess was taken.)
(After the recess the following occurred:)

Page 52

THE VIDEOGRAPHER: The time is 10:46. We are back on the video record. You may proceed.
BY MR. TRISCHLER:
Q Okay. We just took a break. Doctor, you said that you wanted to take some time to review some material. Have you had the chance to do that?
A Okay.
Q Have you had the chance to look at whatever it was?
A Yes, I did. I did.
Q Hold on. That's the only question I asked you right now. Did you talk to anyone while we were on that break?
A No, I didn't.
Q You reviewed while we were on that break?
A Yes.
MR. NIGH: It wasn't really a break for Dr. Najafi.
Q What did we review at the time we went off the record at your request?
A I looked at the USP website.
Q Okay. And did you find anything on the USP website suggesting that the USP monographs

Page 53

were minimum standards?
A So I looked at exact same page that you're looking at, which is USP.org. It's about USP public policy overview of monograph.
Q Did you find anything on that website that we marked the pages of which we marked Exhibit 27 that indicate the USP monographs are minimum standards?
MR. NIGH: Form objection. That document is just one small part of the entire USP.org. You can see the site map which has much more than this little snippet from the website.
MR. TRISCHLER: Is that a proper objection?
MR. NIGH: It actually is, because you misrepresented the document, so absolutely it is.
MR. TRISCHLER: You know better.
MR. NIGH: No. You misrepresented the document in your question just now.
Q Sir, I'm just asking you to tell me where it is published that USP monographs are minimum standards. You made that representation. Where is it published?
A Yes. So I would like to point you to No. 1 where it says (1) monograph in your exhibit.

Page 54

Monograph articulates the quality expectations, quality expectations to anybody familiar with the art; art of synthesis and manufacturing. It means minimum expectation. That's my understanding and that's my pure understanding.

Those quality expectations, it's like, you know, just like the bar that you have to have, you know, and that's a starting point for a medicine including for its identity, strength, purity, performance. They also describe the tests to validate and so forth and so on, which is all -- you can read it as well. That's the minimum standard.

Q And so if we go back to the monograph itself which we had previously marked, I think, as Exhibit 17, you remember the table told us that under that -- it is the next page. Thank you.

The table told us that the acceptance criteria for unknown impurities was 0.1 percent, right?

A Right.

Q And 0.1 percent, that translates to about 1,000 parts per million, right?

A Right.

Q And if we're talking about a 320 milligram tablet and we wanted to convert that to nanograms, that would be about 320,000 nanograms,

Page 55

right?

A Yes.

MR. NIGH: Objection. Scope.

Q So, according to USP, whether it's standards or minimum, maximum or something in between, it's acceptable to have a drug product with unknown impurities of as high as 320 nanograms in a 320-milligram tablet, right?

MR. NIGH: Objection. Scope.

A USP also refers you to ICH guidelines and genotoxic guidelines, and those genotoxic compounds could be as low as, you know, zero.

Q But it could be as high as 320,000 nanograms?

A Could be as high as that level, but the drug would not probably get approved.

Q Well, it would meet USP acceptance criteria, right?

A No, it wouldn't.

Q An unknown impurity -- we just went through the table. An unknown impurity in a 320-milligram drug product can be as high as 320,000 nanograms, right?

A Unknown impurities that are not genotoxic can be as high as, you know, 300,000

Page 56

nanograms. If they are genotoxic, no.

Q I am going to switch gears for a minute.

A And you can refer you to my reference on ICH guideline M7.

Q I didn't even ask you a question.

A It's part of the previous question.

Q You told me at the beginning of this deposition that you'd been retained in the valsartan MDL to offer expert testimony right?

A Yes.

Q Do you remember when you were first retained in the valsartan matters?

A Repeat your question, please.

Q Do you remember when you were first retained in the valsartan matters?

A I think I was retained sometime in 2019; October, maybe September, October 2019.

Q Can you identify the plaintiff's lawyer or lawyers who retained you?

A Yes.

Q Can you identify them?

A They're on the phone. They're on the Zoom.

Q Well, I'd like you to tell me their

Page 57

names, please.

A Daniel, Rosemarie and Brad.

Q Daniel Nigh -- for the record, Daniel Nigh, Rosemarie -- what is Rosemaries' last name?

A Bogdan.

Q And who is the third person you mentioned?

A Brad Vaughn.

Q I'm sorry. Did you say Vaughn?

A Yes. It's the firm Pendley Bovin & Hoffman, I think, or --

Q All right. Have you also been retained by plaintiff's counsel as a consultant in the ranitidine MDL?

MR. NIGH: Hold on. I am going to instruct him not to answer.

MR. TRISCHLER: Can I ask on what basis?

MR. NIGH: Actually, we have disclosed an opinion, so you can ask him. Go ahead.

Q Have you also been retained as a plaintiff's consultant in the ranitidine MDL?

A I have been retained as a consultant in the ranitidine matter.

Q And in this litigation, the valsartan

Page 58

cases, do you understand that claims have been brought against -- well, strike that.

Let me ask you this first: In the ranitidine litigation, do you understand that claims have been brought against brand and generic manufacturers based on the presence of nitrosamines in ranitidine-containing products?

A Could you repeat your question?

Q Sure. In connection with your work in the ranitidine litigation, I'm simply asking you if you have an understanding that in that lawsuit there have been claims brought against both brand and generic drug manufacturers based on the presence of nitrosamines in drugs made by both brand manufacturers and generic.

A I believe so.

Q Do you know how many drug manufacturers and drug suppliers have been sued by plaintiffs in the ranitidine MDL stating their products contain nitrosamines?

A There are many, many. I can't tell you.

Q Is the number more than 75?

A I don't think so.

Q More than 65?

Page 59

A I don't think so.

Q More than 50?

A I don't think so.

Q Can you give me an estimate of how many drug manufacturers and drug suppliers you understand to be part of that case?

A Probably a dozen.

Q Do you know how many drug manufacturers and drug suppliers are part of this case, the valsartan MDL?

A I don't, perhaps a dozen.

Q In addition to the ranitidine MDL and this lawsuit, is it true you're also working for plaintiffs' lawyers in the metformin MDL?

MR. NIGH: Form objection. I am going to instruct him not to answer.

MR. TRISCHLER: What's the basis, Daniel, just so I have it on the record?

MR. NIGH: If he is a consulting witness, there is no opinion that's been disclosed of metformin.

MR. TRISCHLER: Well, I don't know. I'm asking. Are you suggesting he's not a disclosed expert in that case?

MR. NIGH: There's been no experts

Page 60

disclosed in the metformin litigation.

Q Aside from the valsartan MDL and the ranitidine MDL, are there any nitrosamine litigation matters that you're working on where you have been retained to offer expert testimony?

MR. NIGH: And I would instruct that if you were working on any other matters where your expert opinion hasn't been disclosed, that you not answer that question, because it's privileged.

Q Can you answer that question, Doctor?

MR. NIGH: Can you ask the question, any other litigations where his expert opinion has been disclosed?

MR. TRISCHLER: I thought that was the question I did ask. Do you want me to ask it again?

MR. NIGH: No, you actually didn't ask that way, but if you ask that way, then we don't have to worry about the privilege objection.

Q Other than ranitidine and valsartan, have you been retained by plaintiffs in other litigation where your opinions have been disclosed to provide testimony on matters relating to nitrosamines?

A So we are a contract lab and, you know, less than 10 percent of our business comes

Page 61

from litigation support but, yes, we have been retained by other firms regarding nitrosamines.

Q And what other firms would that be?

MR. NIGH: Again, was there an opinion disclosed in any other litigation other than ranitidine and valsartan, any expert reports? Otherwise, this is privileged material and I would instruct you not to answer.

MR. TRISCHLER: I'm just trying to ask a predicate question, whether there are any others.

MR. NIGH: He just said no. I don't know if you heard him.

MR. TRISCHLER: I did not.

A I did not disclose any expert opinion on any other matters.

Q Except ranitidine and valsartan, that's your testimony?

A Valsartan we have not disclosed any expert opinion either. We have not finalized our expert opinion as of yet.

Q Well, that's news to me, because I thought you did file a declaration that brings us here today that contains some opinions and that's what we're here to talk about.

In any event, I think what you're suggesting

Page 62

to me is that you may have valsartan at a later date and you may have other reports and other opinions; is that what you're telling me?
A That's correct.
Q My only question -- only thing I am trying to get to the bottom of is whether there is any other litigation matters involving nitrosamines that you have been involved in where you've disclosed an expert opinion other than ranitidine and valsartan?
A No.
Q The company that you own and operate, as I understand it, is called Najafi Pharma Inc; is that right?
A Najafi Pharma Inc.
Q Najafi Pharma. Sorry about that.
A Same as my last name.
Q Yes, and Najafi Pharma does businesses as Emery Pharma?
A Yes, that's correct.
Q Is Najafi Pharma Inc. a corporation?
A Yes, that's correct.
Q Is it publicly or privately held?
A It's a privately held corporation.
Q Who are the shareholders of that

Page 63

corporation?
A My wife and me.
Q How much of the stock do you own?
A Fifty-fifty.
Q I presume your wife then owns the other 50 percent?
A That's correct.
Q And what is her name?
A Kelly Faranghi.
Q Do you mind spelling that for my benefit?
A Sure. It's F as in Frank A-R-H-A-N-G-I -- G-H-I, and first name K-E-L-L-Y.
Q Since you and Kelly are the sole shareholders of Najafi Pharma Inc, I assume, then, that all revenues generated after expenses go to you and your wife?
A That's correct.
Q In connection with your work as a litigation consultant in nitrosamine litigation, are the fees that you generate and the income that you receive paid to you through the company or is this litigation work something that you do independent of Emery Pharma?
A No, it's paid through the company.

Page 64

Q Can you tell us what total revenues have been generated by Emery Pharma by your work as a paid consultant for plaintiffs in nitrosamine litigation?
A I don't have the exact number, but it's around 200.
MR. NIGH: No, no, no. Sorry. Sorry. I would object. You can ask what percentage of his revenue over the last few years, but you can't ask total revenue numbers.
Q Who would --
MR. NIGH: If you want to ask for this litigation, that's fair, but you can't ask for all litigations.
A No, no.
MR. TRISCHLER: And that's not even a proper instruction for you to give, so just keep putting on the robe as well as acting as an advocate. It's improper, but it doesn't appear that you're ready to stop.
Q Did you -- who would have the information about your company about what revenues Emery Pharma has generated from work in nitrosamine litigation?
MR. NIGH: Again, this goes outside

Page 65

the scope of what is allowable. You can ask about valsartan and the revenues for valsartan, but not for all nitrosamine litigations.
MR. TRISCHLER: Only thing I've asked for the name of a person at the company who would have that information.
A I have that information.
Q So you know the exact dollar amount? I thought you said a few minutes ago you didn't know it.
A No, I didn't say that.
Q Let me ask about some of the records that I received specific to your valsartan work.
MR. TRISCHLER: Can you display what I premarked as Exhibit No. 2, please?
A Yes.
Q Exhibit No. 2 looks to be some form of a retainer agreement. Do I understand that correctly?
A That's correct.
Q And is this the retainer agreement that confirms your engagement --
A That's correct.
Q You've got to let me finish the question, sir; confirms your engagement as a

Page 66

litigation consultant for the plaintiffs in the valsartan litigation?
A That's right.
Q It looks like, if we go to page 4 of this exhibit, it looks like it was signed in October of 2019. Do I have that right?
A That's correct.
Q And somewhere in here I think you requested or your company requested a retainer of $5,000; is that right?
A I guess so, yes.
Q Is that your usual retainer or would that be something that was different for this case?
A It varies.
Q Was that retainer paid, if you know?
A Yes, it had.
Q And the retainer agreement says -- I have to find the right spot, so bear with me.
A All right.
Q I'm looking at page 3, if you could turn there. Thank you. There is a paragraph under background and scope of work. Do you see that, sir?
A Yes, I do.
Q And it says you're being -- Hollis Law is engaging Ron Najafi as a consultant expert

Page 67

witness and Emery Pharma for laboratory activities relating to valsartan NDMA, NDEA, NBMA and DMF.
A That's correct.
Q What is NBMA?
A That's another nitrosamine impurity.
Q Do you know what NBMA stands for?
A Not off the top of my head, but it is -- it could be butyl nitrosol -- n-methyl butyl nitrosamine. It could be n-methyl for amino, so I have to check with my chemistry team what is part of the proposal.
Q Is part of the proposal DMF; what is DMF?
A DMF stands for dimethyl fumarate.
Q And the second part of that or second paragraph under that background and scope section of the retainer agreement says, "While not currently in the scope of work, if any testing of valsartan pills is ordered by clients in the future, such testing will be performed under CGMP/GLP."
A Right.
Q Did I read that correctly?
A That's correct.
Q And the -- see, I'm pretty sure I know what CGMP stands for. That's current good

Page 68

manufacturing practices, right?
A Yes.
Q What does GLP stand for?
A Good laboratory practices.
Q And CGMP and GLP guidelines that you reference in this retainer guidelines specific -- that would have been developed specific by you for your lab or are you referencing or intending to reference general standards for GMP and GLP?
A So Emery Pharma is an FDA-registered, FDA inspected GLP, GMP compliant laboratory and we do perform work that is under GLP, GMP to those standards. It means that you maintain good laboratory notebooks. It means that your equipment -- that their products is going to be tested. It's qualified. It's calibrated. So those are some of the things that, you know, this sentence effectively promises.
Q And I understand that. I guess my question was, are the guidelines that you are referring to in this retainer a guideline of general applicability for all registered labs or are they specifically developed for your lab?
A No, there are a lot of general labs that contract labs could follow GLP, GMP; could be

Page 69

compliant with GLP, GMP and maybe not compliant with GLP, GMP and may do things under R&D condition, so it really depends on the lab.
Q And who published the CGMP and GLP guidelines that are referenced in your retainer agreement?
A This particular -- are you referring to this particular retainer agreement?
Q Well, yes, because that's the only retainer agreement I have.
A I put it together.
Q I know you put it together.
A I have my signature on it.
Q You're not following me. Hold on. You're not following my question, sir. My question was who has published the guidelines that you make reference to in this?
A The guidelines are set by the FDA, by European medical authorities, by ICH.
Q And you go on to, in this retainer agreement, state that if any testing of valsartan pills is ordered in the future, such testing is going to be performed under the guidelines. Do you see what I am referring to?
A Right.

Page 70

Q Prior to the time that you entered into this retainer agreement in October of 2019, had your lab ever conducted any testing of valsartan-containing medications produced by Mylan Pharmaceuticals?
A The answer is we have conducted valsartan testing prior to this retainer agreement.
Q And was the valsartan testing that you conducted, was it using valsartan tablets produced by Mylan?
A I don't recall.
Q Was the valsartan -- and right now I am only asking you about testing you did prior to entering this agreement. Was the valsartan lab testing that was done at Emery prior to the entry of this agreement, did it involve any valsartan containing medications produced by ZHP?
A I do not recall.
Q Did it involve what I'll call the pre-retainer testing, okay?
A Right.
Q Did any valsartan testing that you made reference to that was conducted at the Emery lab involve any other valsartan-containing medications produced by Hetero?

Page 71

A I do not recall and if I did, it would be privileged. It would be under a different, you know, agreement with another law firm.
Q Did any of the testing that you did prior to this retainer agreement involve Aurobindo-manufactured products?
A I do not recall. I don't know.
Q Do you recall if any of the pre-retainer valsartan testing done at your laboratory involved any valsartan-containing medications produced by any of the defendants to this litigation?
A I do not recall the manufacturer's name that we tested prior to this agreement. It could have been any one of those companies.
Q Since you entered into this retainer agreement and became a consultant in this valsartan litigation in October of 2019, have you ever conducted any lab testing on any valsartan medications produced by Mylan?
A I do not recall. We test valsartan. We assign numbers to pills. We have very good chain of custody. We typically -- the operators who do the testing, they have no idea who is manufacturing the pills. There simply there is an ID to it and

Page 72

chain of custody and they get it tested, and I honestly don't know. I don't pay attention to who the manufacturers are.
Q So your lab has done valsartan testing of valsartan medications since entering into this retainer agreement, correct?
A We have done lots of valsartan testing prior to this agreement and we've done more valsartan testing post this agreement.
Q And if I understand your testimony -- I am going to get into the details of it more, but if I understand your testimony so far, what you're suggesting is that as you sit here today providing testimony under oath, you're not able to tell us whose valsartan product you tested in terms of who the manufacturer was?
A No, I don't have that information.
Q Would there be records available in your lab records that would tell you that?
A Yes, there would be records available at our lab that would tell me exactly what the manufacturers are.
Q When did your lab first start doing valsartan testing?
A I think around maybe May of -- April,

Page 73

May of 2019.
Q What was the reason that your lab started to do valsartan testing in April or May of 2019?
A I think it was initiated primarily by the recall of valsartan products.
Q And is it something that your lab did on its own initially or were you retained by somebody to do that testing in April and May of 2019?
A We were retained.
Q And who retained you in April or May of 2019 to do that testing?
MR. NIGH: Again, if this is privileged information and has nothing to do with this case, then I would instruct you not to answer and waive whoever else's privilege you have.
A It is confidential and privileged.
MR. TRISCHLER: Well, I think -- you know, in fairness, I think I am entitled to know who it was in order to determine whether there is any claim of privilege.
A It was a law firm.
Q Was it a law firm representing a plaintiff, representing a manufacturer, a drug

Page 74

supplier; do you know?
A It was a law firm representing plaintiffs.
Q Is that firm that retained you in April or May of 2191 of the law firms that are involved in the valsartan MDL?
A I don't know.
Q Do you know if the lawyer for the firm that retained you is involved in the valsartan MDL?
A We do the testing. We know the nitrosamine. We know the chemistry. We don't really get involved with, you know, sort of the legal aspects of what's going on.
Q I understand. My question was simply -- and if you don't know you can tell me you don't know, but my question --
A I don't know. I don't know, honestly. They may be involved with MDL. They may not.
Q And so are you able to describe for me what type of testing you were retained to do in April or May of 2019?
MR. NIGH: Let me in for a second here. I am going to object. I think all this information is privileged. I appreciate, Clem, Mr. Trischler, trying to understand who the parties

Page 75

are and I think Dr. Najafi just doesn't know whether or not they are related to MDL. I think we do know. It has no bearing on any of plaintiff's counsel and no relation to this MDL, but I don't think that he knows that. Why you ask him sitting here today.
MR. TRISCHLER: I understand and I am not trying to be unfair, Daniel. I'm just trying to -- if we need to raise the issue, I'm trying to understand some of the basic facts of what was done and when so that -- and sort of making a record. I assume if we get into it later, I don't think there's any dispute that we ought to be entitled to know the basic facts of what he did so we can argue relevance and privilege to the Court, and that's all I am really trying to do here.
I think the only question pending at this point is are you able to describe the type of testing that was done in April or May of 2019.
MR. NIGH: No, I think that that's privileged.
BY MR. TRISCHLER:
Q Were reports of -- whatever testing was done, were reports generated?
MR. NIGH: Again, privileged.
MR. TRISCHLER: Well, I didn't ask

Page 76

what the reports disclosed, just whether reports were generated.
MR. NIGH: Again, privileged.
MR. TRISCHLER: So you're instructing him not to answer that question?
MR. NIGH: Yes.
BY MR. TRISCHLER:
Q Were there established lab protocols that Emery had created pursuant to which the April, May 2019 testing was conducted?
MR. NIGH: Again, privileged.
MR. TRISCHLER: See, Dan, I disagree with you there. If there is an established protocol that they have that's part of their everyday, work I think I'm clearly entitled to that. I'm not asking him the results of the testing, but just the protocols that were followed. Those are lab procedures. I don't think -- that's not privileged.
MR. NIGH: You know, for the certification he doesn't rely on testing of the valsartan pills at all whatsoever in any of his testing that he has done, so it's outside the scope and privileged.
MR. TRISCHLER: And I don't want to argue relevancy or privilege with you right now. I

Page 77

am just trying to understand the facts so that we can seek the information later, but the fact that he's not relying on it for whatever opinions he intends to offer at this stage of the proceedings is not determinative. For all we know there may be information that undermines his opinions, but we don't know until we have an opportunity to discover it.
Again, the only question pending at this point -- you've made your objections where you think they are appropriate and I am not arguing any of them, Dan. I am just asking you to reconsider the objection to the question I just asked about whether there are existing lab protocols pursuant to which this work in 2019 was done. I don't think that's privileged at all.
MR. NIGH: I think you asked that question a little bit differently and I think he can answer that question.
MR. TRISCHLER: Tell me how you think it should be asked differently and I will accept that.
MR. NIGH: No, no. I think you asked it differently. My understanding is you're asking do they have guidelines as to how this testing would

Page 78

be conducted. That's different.
MR. TRISCHLER: Well, that was --
MS. HILTON: Not developed for the testing, but do they have guidelines that were in place or existing at the time of the testing.
MR. TRISCHLER: Yes. That's what I'm looking for.
A So what's the question?
Q The question was at the time this testing was done in April or May of 2019, did your lab have existing protocols and guidelines in place that would have governed that testing.
A We follow several guidelines, several procedures from FDA on testing of, basically, nitrosamines, and that's what we use. So it's established testing guideline, you know, with the full following the same guideline procedure controls.
Q Do you have any information -- whatever the valsartan that was tested in April or may of 2019, do you have any idea where it came from?
MR. NIGH: I am going to object to privilege and instruct him not to answer. Actually, I think we have gone far beyond. I think we are

Page 79

going to have to brief this at this point, Mr. Trischler, because even his last answer contained, you know, essentially privileged information. Anything that has to do with testing that has no nexus to this litigation is privileged.
MR. TRISCHLER: Okay. I disagree. You've disclosed this witness as a testifying expert. He's now indicated that he conducted valsartan testing to ascertain nitrosamine levels. He did it in 2019. He's been doing it on an ongoing basis and the suggestion has nothing to do with this litigation. I think it has no factual merit whatsoever, no disrespect intended. So we obviously have a disagreement, but if --
MR. NIGH: We do, and I am going to instruct him not to answer any further. I would just redirect to his opinion. It's simply not how NDMA, how much products have NDMA. His opinion boils down to valsartan-containing products that contain NDMA OR NDEA but the generic equivalent of Diovan or Exforge because they contained NDMA, NDEA. It's as limited as to that. So whatever tests that he's done in other litigations, there is no relevancy stacked on top of the fact that it's privileged. So I am going to instruct him not to

Page 80

answer about any testing that he has done outside of this litigation.
MR. TRISCHLER: Also your instruction applies to what he described and what we have been calling as the April/May 2019 testing. I think he's also indicated they have been testing valsartan on an ongoing basis.
MR. NIGH: That's correct, and my instruction would apply equally to that testing that has no basis in this MDL.
MR. TRISCHLER: So your position, just so I'm clear and I don't have to belabor the record, is that we can agree that the witness operates a research lab that's done testing on valsartan-containing medication for nitrosamine content on a fairly consistent basis since April and May of 2019, some of which may include valsartan-containing medications produced by the defendant in this litigation, some of which may include valsartan containing medications produced by manufacturers and suppliers that are not parties to this litigation, but your instruction is a global one that all of that testing is off limits, according to the plaintiff and that the witness will be instructed not to answer any questions at all

Page 81

about it. Is that your position?
MR. NIGH: I think he's answered he doesn't know which manufacturer, so that's been established already right. Other than that, my instruction would be no further testimony, and I would instruct him not to answer about any further testimony about testing that he has done, since none of that testing was done for the MDL on behalf of the MDL and has no nexus to the MDL. Actually, if we need to brief it, we can.
MR. TRISCHLER: Right. I will just say we disagree. I think it's clearly relevant and probative, but we can save it for a future date. I don't want to belabor the record on it, so let me move on.
MR. NIGH: I understand.
BY MR. TRISCHLER:
Q You talked about or I was asking you about your work in the valsartan MDL. In addition to that retainer, I wanted to ask you about some documents that I received. I received a few invoices from your firm, Doctor, and I've had those invoices marked Exhibits 3, 4, 5 and 6, okay.
MR. TRISCHLER: Can you put up -- I guess we'll start with Exhibit 3.

Page 82

A Okay.
Q It looks like Exhibit 3 is an invoice that's dated August 2, 2001, correct?
A That's correct.
Q This that August invoice you've submitted a bill for six hours of time for document reviews that were apparently done in July of last year; is that right?
A Right.
Q And then Exhibit 4 is dated January 28, 2022; just last week, right?
A Right.
Q And there you billed, submitted an invoice for two hours worth of time that you spent back in October of last year, right?
A Not October, November.
Q Well, it says class certification review October 25, 2021?
A Right. Right. Exactly.
Q So what does that mean, class certification review October 25, 2021?
A So this is the -- pertains to my expert report on the class certification primarily.
Q I wasn't sure. Is there some -- I don't know what "class certification review" means.

Page 83

What did you do over those hours?
A The expert report that you were looking at earlier, essentially, review of documents, review -- you know, putting that together, putting the expert report together and putting the package of citations and everything that needs to be that you all have in your hands together.
Q Okay. And then the other invoice that I have is Exhibit 5. It's dated January 31, 2022, which is just a few days ago, right?
A Right.
Q And you've got two more hours that you billed for review of class certification final declaration review in November -- on November 4, 2021, right?
A Right.
Q I guess you spent two hours reviewing that declaration on that date?
A Right, but this is reviewing a lot of the citations, reviewing the -- you know, just preparing. This is just preparation for today's call.
Q Okay. And then the final invoice that I received is Exhibit 6. We marked that. It's

Page 84

dated February 1, 2022, and you've got a bill for about 15 hours of time?
A It's, again, reviewing for today's call and refreshing my memory on the various citations that I'm quoting and all of that.
Q Right. So it looks like you spent about 15 hours --
A Right.
Q -- preparing for this deposition?
A Exactly.
Q And when you were preparing for this deposition, who were you preparing with?
A Myself --
Q And --
A -- and I also spent some time with the plaintiff's lawyer discussing the deposition.
Q And which lawyer would that be on the plaintiff's side?
A Rosemarie, Daniel, Brad and Layne.
Q So I assume these invoices, then, that we have that we marked as exhibits 3 through 6 would accurately reflect the time that you spent and that you devoted to this valsartan project since you were retained in October of 2019, right?
A This is not all of them. This is

Page 85

primarily just specific to this expert report that we did.
Q Well, I am interested in all the time and work and billing that you have submitted in connection with your working in valsartan MDL. So this is just a drop-in the bucket?
A This is a portion of the bills that we have given. We haven't shared all the bills.
Q Why not?
MR. NIGH: That's a legal question. We objected and provided the reasons for that objection. His opinion here today is limited on his class certification and not his liability on things.
Q So let me ask you about the declaration itself. You have -- I marked the declaration as Exhibit No. 1. Do you have a copy of it there or do you need to have the --
A I have it.
Q You have it?
A Yes, I do.
Q All right. And so this is a declaration that has your name and your signature attached to it, correct?
A Correct.
Q And it's not on the letterhead of

Page 86

Emery Pharma, is it?
A No, it's not.
Q It's not on your personal letterhead, is it?
A No, it's not.
Q Was this something that you personally prepared or was this prepared by the lawyers?
A No, I personally prepared the document.
Q Every word of this is your words?
A Yes, it is.
Q No help from the lawyers?
A No help.
Q And as I read the declaration, it appeared to me that there were two opinions contained in this declaration. The first one was that you suggest that NDMA and NDEA should not be present in any drug, am I correct that in stating that sort of opinion that you hold and you expressed in this declaration?
A Please repeat your question. I lost track.
Q Yeah. I was just trying to summarize what I think your opinions are that are contained in this declaration and I want to make sure I got it

Page 87

correct. So what I was saying was --
A Yeah.
Q -- in this declaration --
A Yeah.
Q -- you state that NDMA and NDEA should not be present in any drug. Is that an opinion that you hold?
A NDMA and NDEA are carcinogenic mutagenic compound that should not be present in any drug period.
Q And then the second opinion that I saw in this declaration was that you suggest that the presence of a nitrosamine impurity in a generic drug product renders that --
A Could you point to that? Your screen is frozen.
Q Point to what, sir?
A Point to -- you're showing me a document on this screen.
Q No, I wasn't. We can take the document down.
A Okay.
Q You have the report in front of you.
A I thought you were quoting from my declaration, but go ahead.

Page 88

Q No.
A What's your question?
Q I am trying to ask you a question. In your declaration do you offer the opinion that the presence of any nitrosamine impurity in a generic drug product renders that product not equivalent to the reference listed drug?
A Absolutely.
Q And do you agree that those are the opinions that you set forth in your declaration and that you intend to offer in this matter?
A Absolutely.
Q Are there any others?
A No generic drug should contain any mutagenic compound, particularly NDMA and NDEA and, essentially, any nitroso compound. They are cohorts of concerns and their limits should be zero.
Q And that was the first opinion that we went over. Other than those two opinions, are there any others that you intend to offer?
A I might have opinions to offer in my full expert report which will be coming shortly, but what you see for now is what I think I have, but I will have other opinions as well.
Q I'm sure we will all wait with bated

Page 89

breath for the next report, but at this time at this state of litigation, those two opinions are the stated opinions that you intend to offer; is that right?
A Yes.
MR. TRISCHLER: Dan, can we take a five minute comfort break?
MR. NIGH: Yes. Let's take ten minutes.
THE VIDEOGRAPHER: The time is 11:41. This concludes Media No. 2.
(A recess was taken.)
(After the recess the following occurred:)
THE VIDEOGRAPHER: The time is now 12:03. This begins Media No. 3. You may proceed.
BY MR. TRISCHLER:
Q Doctor, allow me to cover a few additional background issues with you, if I can. As I understand it, your background and education is in the field of chemistry, correct?
A That's correct.
Q I was provided with a copy of a CV. I've marked it as Exhibit 7.
A Okay.

Page 90

MR. TRISCHLER: Can someone put it up for me, please. Can you go to the next page.
Q If you need more time, tell me and continue, please.
A I am familiar with my CV.
Q All right. And is this a -- what we marked as Exhibit 7 a true, correct and accurate summary of your qualifications and credentials?
A That's correct.
Q In the copy of the CV that I received, I did not see any list of publications. Do you maintain a list of publications?
A It should be. It should be there.
Q Can you flip through? Maybe this is a different one than what I had with the report.
A Maybe this is a different one.
Q Is that the end of the document there?
THE VIDEOGRAPHER: There are 13 pages. Do you want me to keep flipping through or do you want me to when you're ready for the next one?
MR. TRISCHLER: Yes. Keep flipping through, because if it's more than five pages, then it's different than one I have.
A Now you see the publication.
Q Yes. Okay. The copy that I was

Page 91

looking at did not have that. All right. Thank you.
A What is your question?
Q As far as you know, this version of the CV we marked as Exhibit 7 is current, up to date and accurate, right?
A Right, as long as you can show me everything else, because it sounded like you were missing some parts of it. I only see two publications on your exhibit.
Q Well, we said we can flip through the rest if you like. That's why I asked if you wanted to.
A Yes, flip through it.
THE VIDEOGRAPHER: This is page 6, Doctor. Just let me know when you're ready for the next page.
THE WITNESS: Yes. Go ahead. Go ahead. Yes. Uh-huh. Okay. Yes.
THE VIDEOGRAPHER: There's two more pages.
A Okay. I think you have everything.
Q So we're good? In terms of what we marked as Exhibit 7 is the up to date, current and accurate summary of your qualifications, right?

Page 92

A Correct.
Q Good. And what I remember reading is that you obtained a bachelor's and master's in organic chemistry from the University of San Francisco, right?
A Correct.
Q And I think it was in 1998 you got your PhD in organic chemistry from U.C. Davis?
A That's correct.
Q And after completing your PhD you went to work as a research scientist for a few chemical and pharmaceutical companies before starting your own business around 1996?
A That's correct.
Q And the company that you started in 1996 was a company called CP Lab Safety; do I have that right?
A That's correct.
MR. TRISCHLER: You could take the CV down, sir.
Q How long did you run CP Lab Safety?
A Probably around two years, two or three years.
Q Did CP Lab Safety develop or manufacture drug products?

Page 93

A No.
Q Did CP Labs hold any new drug applications?
A No.
Q Did CP Labs hold any abbreviated drug applications.
A No.
Q Did CP Labs hold any or were they responsible for any drug master files?
A No.
Q While at CP Labs, were you or was your company at all involved in the synthesis, manufacture or testing of API for drug products?
A No.
Q At CP Labs did your company have any role in the formulation, synthesis, manufacture, production or testing of angio tensin receptor blocker medications like valsartan?
A So at CP lab I started another pharmaceutical company called NovaBay Pharmaceuticals and that is immediately following CP Lab and that company effectively was incubated within CP Lab and within NovaBay I had multiple interactions with the FDA. We manufactured product according to CGMP and we put products on the market.

Page 94

And prior to CP Lab, I worked at a pharmaceutical company that was heavily involved in GMP manufacturing and drug product, drug substance and that one of the companies I worked for, Applied Biosystems, in fact, you know, we had a challenging impurity that was causing a lot of problem and I was responsible for finding that impurity and solving a major problem that led to an award, you know, amongst 1,300 PhDs. This is back in 1994.

So -- but, you know, I don't have to have experience in, you know, ARBs to know the molecule. I can synthesize ARB personally.

Q Are you finished?

A Yes, I am.

Q All right. Then let me see if I can get you to answer my question. At CP Labs did your company have any role in the formulation, synthesis, manufacture, production or testing of ARBs like valsartan?

A No. At CP lab we did not have any ARB manufacture.

Q You said that -- if I can unfold some of that commentary that you gave me, was that CP Labs was eventually folded into NovaBay Pharmaceuticals, another company that you started?

Page 95

A No. CP Lab is, you know, existing company right now and it's a standalone company. NovaBay was incubated within CP Lab and NovaBay got its start from CP Lab.

Q So CP Lab still exists today?

A Yes it does.

Q Do you have any affiliation with CP Lab?

A I own 50 percent of CP Lab.

Q Who owns the other half?

A My wife.

Q What's the business of CP Labs today, do you know?

A CP Lab manufactures patented product called ecological funnel, which is product that I invented while I was at Applied Biosystem and that patented product is the major product of CP Lab and they manufacture it in the United States and they export it around the world including China, Korea, Japan and elsewhere.

They also distribute chemicals, distribute safety product. So you can visit CPlab.com and take a look at it.

Q What is an ecological funnel?

A It's a tunnel that prevents

Page 96

evaporation of solvents from the fume. It's an environmental product that prevents pollution outside of laboratory. It prevents evaporation of toxic substances, including mutagenic -- potentially mutagenic compounds going into the atmosphere and into the neighboring localities. And ecological funnel is in use right now in, I would say, 90 percent of pharmaceutical companies worldwide.

Q When did you start NovaBay?

A NovaBay was incubated within CP Lab around probably 1998; '97, '98 and officially it became a company in the year 2000, and I took the company public in 2007 and I left. I sold my shares and left NovaBay in 2015 and started Emery Pharma. And Emery Pharma, actually, again was incubated within NovaBay starting at 2011.

Q Am I correct that NovaBay produces antibacterial products for the eye care and skincare markets?

A That's correct. That's some of their products.

Q While you were at NovaBay, did the company do any work on the formulation synthesis, manufacture, production or testing of ARBs?

A We did not manufacture, synthesize,

Page 97

formulate any ARBs at NovaBay.

Q Did -- while at NovaBay, did that company ever prepare or submit an abbreviated new drug application for any drug product?

A We did not prepare or submit any abbreviated new drug application. However, we submitted many INDs, investigation of new drug, and we also submitted many 510-Ks from the drug or device division of the FDA.

Q I guess was that because the focus at NovaBay was to try to develop its own line of --

A Product.

Q -- probial products?

A Right. We were not a generic manufacturing -- we were not a generic pharmaceutical company.

Q So at no time at NovaBay were you involved in synthesizing API for a generic formulation, correct?

A We could have, but that was not the mission of the company.

Q So it was never done?

A Never done.

Q And then at some point did you say Emery Pharma was intubated?

Page 98

A Incubated.
Q I'm sorry?
A Incubated.
Q Incubated. I said intubate. That would not be correct.
A I heard "intubated."
Q Right. That's what I said. I did say that. That was not correct, so I apologize.
And then eventually Emery Pharma became a standalone company that you operate to this day, correct?
A Correct.
Q And I think that if I understand what you've previously described for us, the mission statement and the function of Emery Pharma is to provide research laboratory services that meet the CGMP and GLP standards for quality?
A Emery Pharma is a FDA registered, FDA inspected DMB, GLP compliant contract research organization and our mission is to help save lives and save the environment.
Q Does Emery Pharma develop or manufacture drug products?
A Emery Pharma? That's not within the mission of the Emery Pharma, no. We can, but we do

Page 99

not.
Q Does Emery Pharma hold any new drug applications?
A No, we do not. Our clients do.
Q Does Emery Pharma hold any abbreviated new drug applications?
A We do not, but our clients do.
Q Has Emery Pharma ever prepared a DMF, submitted a DMF?
A We do not, but we help our clients essentially submit DMF and NDA and IMD and we participate in their FDA meetings when necessary.
Q And I'm sorry. I think it was probably due to sometimes there's sound that goes in and out in the computer. You said you help clients with submissions of what was that again?
A New drug application, abbreviated new drug application; DMF filings; you know, support. Just about anything that the client needs, we help. We support them.
Q And how long has Emery Pharma been in business?
A Since 2011, ten years.
Q Who are the clients for whom you've help submit new drug applications or abbreviated new

Page 100

drug applications?
A That's confidential information. I wouldn't be able to share with you.
Q So you'll say that you have experience helping to prepare ANDAs and NDAs, but you won't tell us who you did it for?
A Yes.
Q Have you ever assisted a client in preparing a DMF?
A Personally, no, but some of my employees might have.
Q In your career, sir, have you ever published any peer-reviewed literature related to nitrosamine impurities in pharmaceuticals?
A Yes, we have. We filed a citizen petition which was previewed by FDA and the response we got from the FDA was they had agreed with our findings, so I just would consider that very peer-reviewed.
Q My question wasn't have you ever submitted a citizens petition. My question was have you submitted literature for publication in a scientific journal that's been peer reviewed and accepted that related to nitrosamine impurities in pharmaceuticals?

Page 101

MR. NIGH: Objection. You can answer.
A We have not filed any nitrosamine-related publications in a peer reviewed journals of our FDF filing.
Q The list of publications that were attached to your CV that we marked as Exhibit 7, do any of them feel with nitrosamine impurities in pharmaceuticals in any manner or form?
A I do not believe they do.
Q Have you ever drafted a manuscript related to nitrosamine impurities in valsartan for publication in a peer review journal?
A We have drafted publication regarding NDMA and nitrosamines, but not published.
Q Have you submitted a manuscript for publication?
A No.
Q Why not?
A It's confidential. It's related to another matter that we are working on related to ranitidine.
Q Will you provide it to me?
A Daniel? I suppose I can.
MR. NIGH: We would have to see what the document is. I think he just amended his answer

Page 102

at the end to say it's for ranitidine and your question is for valsartan.
MR. TRISCHLER: I think the question was --
A It's under --
MR. TRISCHLER: Hold on. Hold on. I think my memory is not infallible, Daniel, but what I was basically asking is whether he's ever drafted a manuscript that relates to nitrosamine impurities in pharmaceuticals. I may have said valsartan, but my intent was broader, and so it sounds like something. The question is can I see it. It's not been produced thus far.
MR. NIGH: We would examine the document before we respond and answer to that.
MR. TRISCHLER: Well, it was subject to the notice of deposition in this case. In the deposition notice served in connection with this deposition, I asked that the witness come here with all publications relating to nitrosamines. That would clearly -- this manuscript that he's described would clearly be responsive.
MR. NIGH: I think you had our response an hour ago.
MR. TRISCHLER: I'm sorry. Unless you

Page 103

want to continue the deposition, I mean, this is my chance to depose him on it.
MR. NIGH: I believe that 48 hours ago we served our objections as clearly outside of the scope of anything that is he's proffered in terms of testimony in his expert here today.
MR. TRISCHLER: Well, as far as outside the scope of his declaration, I disagree, but I guess we will be taking it up again.
Q So you do have a manuscript --
MR. NIGH: And just to be clear -- sorry. Since you're saying something about taking it up again, just so you understood too, I haven't even looked at this document. So to the degree you're asking about draft documents and publications, obviously it would have potential privilege as well.
A It's ranitidine related, but it's nitrosamine.
Q Well, you've publicly disclosed the existence of this manuscript, have you not?
A No.
Q Well, can you put up Exhibit 8 for us, please. Do you recognize Exhibit 8?
A Yes, I do.

Page 104

Q What is it?
A It's sort of a summary that one of my team members wrote regarding our filing of our citizen petition regarding ranitidine and how we came about it, how we found the problem and how we reported it to the FDA and how FDA actually agreed with us and responded to our petition in a positive manner. So that's really just the story of that. There's nothing about this that contains anything about that draft publication.
Q So this is what we have marked as Exhibit 8, is basically a press release that was issued by Emery Pharma, correct?
A Correct.
Q And I think this press release is available on your website?
A Website. It's not a press release. It's a blog.
Q All right, but this document and this disclosure is on your website --
A That's correct.
Q -- for the public at large to view?
A Yes.
Q And in this document don't you state or indicate that you're preparing a manuscript for

Page 105

publication on the issue of nitrosamines in pharmaceuticals?
A Right.
Q And if you could go to page 2 of this document.
A Okay.
Q Can you highlight the second full paragraph for me, please. Thank you. Are you able to read that, sir?
A I'm reading it. Yes, I'm reading it.
Q So. Emery Pharma has publicly disclosed that it's been testing valsartan, losartan and other ARBs for nitrosamines since the early 2018 time period, correct?
A That's correct.
Q And there's nothing in these public comments that you've made at the testing that we've not been provided with it's something that's done for litigation or confidential. You've told the free world about it, right?
A We mentioned that we have been doing that, but we haven't disclosed the results. The results are confidential.
Q You are not a pathologist, true?
A Say that again, please?

Page 106

Q You are not a pathologist?
A Pathologist?
Q That was my question.
A No, I'm not a pathologist.
Q Are you a medical doctor?
A I'm not a medical doctor.
Q Are you a toxicologist?
A I'm not a toxicologist.
Q Is it fair to say you're not a epidemiologist and you do not have any specialized training or expertise in the field of pharma epidemiology?
A I am not a epidemiologist or any of that.
Q Have you ever conducted and published any peer-reviewed research on the carcinogenicity of NDMA?
A No, I have not.
Q Have you ever conducted and published any peer-reviewed research on the carcinogenicity of NDEA?
A No, I have not.
Q Since you have no medical training, I assume you do not diagnose cancer in patients; fair to say?

Page 107

A I am not a doctor.
Q And in this litigation I understand you have not been designated as a witness on the issue of causation, true?
A I am not a medical doctor.
Q Right. And you're not going to testify -- well, we can agree you're going to be offering causation opinions in this matter, correct?
A Explain to me what causation, what your definition of causation here.
Q You're not going to be offering any opinions that exposure to NDEA or NDMA did or can cause cancer in humans?
A No, I am not offering any opinion on the toxicology opinion on the NDEA or NDMA.
Q Have you ever published anything on the requirements for a proper drug master file?
A No, I have not published any requirement on anything on the requirements for drug master file.
Q Have you ever published anything on outlining the regulatory duties and responsibilities of a generic drug manufacturer?
A We're not in the publication business. We have not published anything. We are a contract

Page 108

research laboratory testing facility with a lot of experience in drug testing and impurity testing and genotoxic testing.
Q Have you ever published anything or given any lectures or speeches on the critical review of the CMC sections and requirements for a abbreviated new drug application?
A I have. I was invited to give a presentation at a drug impurity symposium for generic manufacturers and that presentation is actually available. It's on the -- it should be online YouTube or various other places.
Q Is it referenced on your CV?
A No.
Q When did you speak at this symposium?
A Probably early 2020, maybe mid 2020. I can't recall.
Q We talked a little bit about Emery Pharma's status as an FDA registered research lab. What did you have to do in order to obtain that registration, if anything?
A You basically submit an application to the FDA and you register yourself with the FDA, and as a result you become subject to FDA inspection.
Q When did you -- when did your lab

Page 109

complete that application?
A I think maybe 2016, 2015, some time frame.
Q When did you obtain the registration; do you know?
A No, I don't, probably within a few months.
Q How many FDA inspections have taken place at your facility since?
A We've had two inspections from the FDA.
Q When were those inspections?
A I can't recall; 2018 maybe one, 2021.
Q Were there any Form 483 issues following those inspections?
A In our second inspection we had a Form 483 filled, yes.
Q That was the most recent one in 2021?
A That's right.
Q What was that for?
A It was primarily for, you know, making sure our data gets backed up and we have -- we do sufficient due diligence to make sure the data that we generate gets backed up into a secondary backup drive. So we have remedied that, and also to make

Page 110

sure that our bend were open when we go to various instruments, every user will have its own individual log in, but we had no issues whatsoever on any of our testing, any of our releases, any of our products that are on the market.

There were just no issues on testing, but just procedurally just data management, primarily backup, and also specific user log-in, and both of those have been remedied.

Q You said something that piqued my curiosity, because I did not understand this to be within the scope of anything you did. You said something about our products. It was my understanding that Emery Pharma does not manufacture or sell any drug products. Am I wrong?

A No, you're not. We do not sell or manufacture any drug product. However, we do release them. So, another contract manufacturer comes to us for a manufacture or a manufacturer comes to us and says, please test my compound and release them according to the guidance, ASP guidance or GMP/GLP guidance.

So we officially release them and we identify the drug, we identify their impurities and we release them. So releasing is a terminology that's known to

Page 111

the FDA. It means it is ready to be sold into the market.

Q Okay. And what you've suggested to me is that in connection with the 2021 inspection, FDA issued a 483 to Emery Pharma finding that certain aspects of it or recordkeeping did not comply with good laboratory practices, correct?

A What I said was that certain parts of our data backup, data storage and backup did not comply with the regs, and really it was a risk management issue and their question was what happens if there is an earthquake and then we lose all the data.

So it needs to be backed up into the cloud so in case of an earthquake, in case of fire we have data that we can go back to.

Q Right. A form 483 is issued by an FDA inspector after an inspection when that investigator observes any condition that in his or her judgment might constitute a violation of the Food, Drug, and Cosmetic Act or its related regulations, right?

A That's correct.

Q And so what you're telling me is that in 2021, your FDA-registered lab was found to have conditions that in the opinion of the investigator,

Page 112

constituted violations of the Food, Drug and Cosmetic Act and its regulations as it related to data management and data maintenance.

A What I said was the 483 -- first of all, in our first inspection 2018 we had no problem, no issues. In 2021 this issue came up that we need to back up our data into the Cloud and it is really part of the data management. And they basically said we can continue our, you know, releasing commercial products; we can continue our work. We just need a commitment for you to get that done; and since then we have gotten it done.

Q And so were any warning letters issued following 483s?

A No.

Q Did -- what is Emery Pharma's status with the FDA today?

A We are in the process of making those data managements happen and they're completely satisfied with that.

Q And so one of the things I take it you learned from that most recent inspection, if not earlier, was that data management, data preservation and documentation are extremely important as it relates to product testing, product release and

Page 113

product validation measures.

A Data storage and back up are important primarily -- you know, it's part of their risk management strategy data integrity program making sure the data is always there. You know, if God forbid the facility catches fire or there is an earthquake, we want to make sure the client's data are there somewhere else. And that's something that we had a backup system on the premises, but that was not acceptable to them.

Q So, understanding the importance of data preservation --

A Into the cloud. They wanted an offer side data storage.

Q Let me ask my question, please.

A Sorry.

Q You're understanding the importance of data preservation, I'm sure, then, you can tell us with absolute certainty that all of the records -- that there will be records relating to all of the valsartan testing that your lab has been doing since early 2018, correct?

A That includes every data preservation that that we have ever generated needs to including valsartan that needs to have it back, have a back up

Page 114

outside of our facility.
Q That would mean you'd have data on the acquisition of samples, correct?
A Data on everything; acquisition. You know even if somebody deletes the data or what have you, everything needs to be backed up.
Q And so it needs to be backed up and you've done that on the valsartan testing you have data on acquisition of samples, correct?
A Acquisition of all samples including valsartan. All samples need to have an off site backup facility.
Q You'll have data of custody for all valsartan samples?
A Yes, we do.
Q You'll have standard point operating procedures and policies outlining the protocol that weren't followed in connection with the test methods that were used on the valsartan products, right?
A As an FDA registered, FDA inspected GLP/gmp-compliant lab, everything we do is SOP driven. So we have SOP's on everything.
Q Because you can't conduct a test and then develop the protocol later, right?
A No.

Page 115

MR. NIGH: Objection.
Q So you would be able to provide us with a protocol pursuant to which all this testing was done, correct?
A If it's not privileged, yes.
Q And do you have -- and you certainly have all the test results for all of valsartan samples that have been tested since the early 2018, right?
A Absolutely. We have the test results and we have reports, everything. If it is not privileged, it would be available.
Q I'll represent to you that the valsartan issue came to the attention of the FDA in June of 2018.
A Right.
Q And your public statements that -- one of which we marked as Exhibit 8 is you started testing valsartan in early 2018. Are you suggesting that you were doing valsartan testing for nitrosamines prior to the time the FDA was even aware that there was a potential issue?
MR. NIGH: Form objection.
THE WITNESS: Should I answer?
MR. NIGH: Yes.

Page 116

A So initially the valsartan issue was brought to our attention by a pharmacy out of Connecticut called Valisure. I think we mentioned their name in some of our blogs and big releases and they brought it to our attention. They wanted to test valsartan and they wanted us to test it for them. They had some testing mechanisms and they wanted us to confirm that. We did draw some samples for them, some pills and we did confirm that. That's our beginning of our engagement in the valsartan arena and that was in 2018.
In 2019 we got engaged by law firm that is not on this call, I believe, and they are -- so a lot of the work we did relates to that but, yes, 2018 was our initial work with valsartan.
Q And so -- thank you. That makes more sense to me now. So the initial work that your lab was doing with respect to analysis of valsartan was done at the request of Valisure, not a lawyer?
A No.
Q Bad question on my part.
A That's correct. The initial work we did on valsartan was done at the request of Valisure.
Q And you would have, consistent with

Page 117

your labs, stated desire to follow good laboratory practices, you would have all of the chain of custody sample, acquisition data, protocol data, test validation data and testing summaries from that Valisure work?
A Yes, I do.
Q None of which has been provided to me, right?
A I don't believe so.
Q Do you know what the results of that work was, what nitrosamine did you test and what were the results?
A You know, I wasn't sure if any of these things are subject of our -- you know, my declaration, but the results were very high levels of nitrosamines, high levels of NDMA in the thousands of nanograms.
Q Do you know whose valsartan you were testing?
A No.
Q In 2018 at the request of Valisure?
A No, I don't. We have records of that. We should be able. Right off the bat, I don't. It might have been Mylan, Teva, Aurobindo, a number of manufacturers we might have been testing.

Page 118

Q If we go back to your declaration for a minute -- bear with me a minute. My exhibits disappeared from my screen, so we have to find it again. If we go to your declaration, we marked it as Exhibit No. 1?
A Would you mind? I'd like to take a quick break, five minute break.
MR. NIGH: Yeah, let's take a ten minute break.
THE WITNESS: Ten minute break? Okay.
THE VIDEOGRAPHER: The time is 12:47. This ends Media 3.
(A recess was taken.)
(After the recess the following occurred:)
THE VIDEOGRAPHER: The time is now 1:00. This begins Media 4. You may proceed.
BY MR. TRISCHLER:
Q I wanted to ask you a couple followup questions on some of the issues that we covered before the last break, Doctor. We talked about the 2021 FDA inspection of Emery Pharma. Do you recall that?
A Yes.
Q And what I wasn't clear about is what

Page 119

is the current status of that 483, is it open or closed?
A It's in the process of closing, because what happens is you're working toward getting, basically, backup system, Cloud system essentially working, you know, and validated an all of that. So that's been in the process of implementation and validation as we speak.
Q So "in the process" means that it's still open?
A It's still open.
Q And is your lab on OAI status?
A What's OAI?
Q Official action indicated, I think is what it stands for.
A I have to check with my QA people.
Q Was an establishment inspection report issued; do you know?
A I don't know.
Q What -- and then going back to your early valsartan work in the early part of 2018, you said that that was prompted by a contact from Valisure that asked you to do some testing. Can you tell me who or what information you received from Valisure that caused them to be interested in

Page 120

testing valsartan before the FDA was even aware of an issue?
A So, you know, to be very frank to you, I don't know whether it was done before FDA official recall or after. I would have to check on that, but I was contacted by the president of Valisure David Light and he wanted us to check the levels of NDMA in valsartan.
Q And you agreed to do that at his request?
A And he had data already. He also had GCMS data that showed high levels of NDMA genotoxic compound, and so I was very concerned because actually my mom was taking valsartan a few years ago, so I agreed to do the work. We might not have even charged them.
I think we probably charged them, I don't know, but we ran the same pills that they had ran and we corroborated their data that indeed there were high levels of NDMA in valsartan, and we might have tested for NDEA as well. I'm not sure.
Q What test method did you utilize during that initial testing?
A We used two or three official FDA methods that has been published. I think we used

Page 121

one of those methods.
Q Well, the FDA didn't publish -- this is the thing that's confusing to me trying to piece together the timeline. FDA didn't publish a test method for nitrosamine testing until the fall of 2018.
A Right.
MR. NIGH: Form objection.
Q So that's why I asked what test method were you and Valisure running.
A I would have to get that. I don't know. For the purpose of this deposition I really was not prepared to discuss any of that, but I am not prepared. It's not in my declaration.
Q So let's go to the declaration, if I can. It's paragraph -- first part I want to talk to you about is paragraph 2 of the declaration I think you said you have in front of you, Doctor.
A If you want me to elaborate on that, a lot of that was published in citizen petition by Valisure and I think some of our data I think he mentioned the data levels and all of that and the methods may be actually there as well.
Q Were you talking about the Valisure petition relating to ranitidine?

Page 122

A Valsartan. I think they did have something on valsartan as well.
Q Did you ever file a citizens petition related to valsartan?
A No.
Q And when I say "you," I also mean Emery Pharma?
A No.
Q You think Valisure did?
A Maybe I'm mistaken. I think they have. You can Google it. I may be mixing it with their citizen petition relating to ranitidine.
Q I'm glad you brought it up, because it sort of led to another question that I had that wasn't clear to me.
You were quick to tell me that part of the mission statement of Emery Pharma is to save lives and preserve the environment. Do you remember telling me that?
A FDA -- I mean Emery Pharma's mission is to helping our client save lives and save the environment.
Q And that was part of the rationale behind your issuance or decision to prepare and submit a citizens petition relating to ranitidine?

Page 123

A We filed -- a lot of the work we did on ranitidine was done at our own expense, at our own behest primarily for the safety of the public. And we do that all the time; public comes to us and they want us to look at something. If they don't have the proper funding, we do it at pro bono and we check the drug for various impurities and problems.
Q But the work you're doing in ranitidine and valsartan is not pro bono, is it?
A So some of the work may be pro bono. A lot of the work that we did on ranitidine citizen petition, almost 100 percent of the work that was done for citizen petition was pro bono.
Q Okay. Why did you never submit a citizens petition with respect to valsartan?
A I think there wasn't any necessity for that. I think there was -- you know, obviously valsartan, it was recalled and I think Valisure was making a lot of noise, so it was already the public was alerted. And my goal as the CEO of Emery Pharma is if there is a problem with a drug, I will alert the FDA through some form of petition, and we recently actually filed a citizen petition on vitamin B6. You may be taking vitamin B6. You may want to read it; and, again, entirely at our own expense.
Q Is that your second citizens petition then that you were submitting?
A Yes.
Q Have there been any others since then?
A No.
Q And you said Valisure was making a lot of noise about valsartan, but have you ever seen a citizens petition from them?
A I don't recall.
Q With regard to valsartan?
A My memory is failing. I think -- I don't think valsartan -- I mean, you guys can google it, whether Valisure filed any citizen petition on valsartan. I don't think so. I think they just made a lot of press release, but I think the valsartan was removed from the market primarily due to Novartis finding genotoxic compound NDMA in valsartan from GMP and then effectively FDA was alerted. I think that's how the things kind of -- how sort of everything fell into the, you know, basically the recall.
Q Did you have any -- have you ever had any communications with Novartis about valsartan testing?

Page 124

Page 125

A None.
Q Have you ever had any communications with Novartis about Diovan testing?
A None.
Q Have you ever had any communications with Novartis about Exforge testing?
A None.
Q So going to paragraph 2 of your disclosure or declaration -- excuse me, I want to ask you about the last sentence in particular where you talk about the methodologies that you employed in formulating your opinions in this case and you write, "These methodologies used in formation of my opinions are also used by Emery Pharma in making recommendations to our pharmaceutical clients." Did I read that correctly?
A Yes. Just let me read it. Yes, I agreed with that.
Q And based on what you already told me, I take it you're not going to tell me who your pharmaceutical clients are you are referring to in paragraph 2?
A I cannot. We are under confidentiality.
Q So you can suggest that you're

Page 126

following a methodology that you employ about your clients but then conveniently not tell me who the clients are, right?
A We are under obligation from the clients not to disclose their name.
MR. NIGH: Form objection.
Q Are any of these clients defendants to the ranitidine litigation?
A No.
Q Are any of them defendants to the metformin litigation?
A No.
Q Are any of them defendants to this litigation, if you know?
A No.
Q Are any of the unknown undescribed clients that you make reference to, are any of them generic drug manufacturers?
A No.
Q Did any of them manufacture ARBs?
A No.
Q So you don't have any clients that you would be advising on the contents of an abbreviated new drug application, correct?
A We do have clients that we advised on

Page 127

the contents of new drug application and abbreviated new drug application. However, none of them are the defendants. None of them are the plaintiffs. None of them are manufacturing ARBs as far as I know and, you know, these are -- we work on mostly branded products, some generic, sort of modified generic, branded generic but nothing to do with ARBs.
Q Well, what generic -- excuse me. What generic products are you working on with generic drug manufacturers?
A I can't think of it right now. I mean a number of them -- there are a number of products that we are working on.
Q Well, if these products have a patent there is no secrecy to the identity of the active pharmaceutical ingredient that you're working on with the --
A I can't recall off the top of my head what generics we're working on.
Q So as you sit here today you can't tell me a single generic product you're advising a client about?
A No.
Q Have you ever told any of your pharmaceutical clients who manufactured generic

Page 128

drugs that their products are adulterated if their impurity profiles do not match the RLD?
A I have told our clients that if their impurity profile contains a genotoxic compound, we will let them know.
Q Thanks. That wasn't my question. My question is have you ever told your clients that they will be producing an adulterated generic product if they have an impurity profile that does not match the RLD; is that advice that you've ever given to your pharmaceutical clients in the real world?
A Okay. So, here is my answer. If their impurity profile -- you know, their impurity profile may not match the RLD. However, if their impurity profile contains genotoxic compound, we will let them know and we will help them to prevent formation of genotoxic compound.
Q Okay. That's fair. So the mere differences in the impurity profile alone does not make a drug adulterated?
A Right.
MR. NIGH: Form objection.
A Mere --
THE WITNESS: Can I respond, Daniel?

Page 129

MR. NIGH: Yes.
A A mere difference -- we have repeated this question many times. I will repeat it. Hopefully you guys can go back and see I am very consistent. Mere difference in the impurity profile so long as there is no genotoxic compound, it's fine.
Q And the fact of the matter is the FDA permits variability in purity, size, strength and other parameters when evaluating an abbreviated new drug application, agreed?
A FDA allows variability in the impurity profile with respect to the reference listed drug as long as it does not contain genotoxic compound --
Q And we talked about --
A -- namely nitrosamines.
Q We talked about the acceptance criteria for impurities as published in the USP being no more than 0.1 percent. Do you remember that?
A I remember the acceptance criteria of the USP not showing any NDMA and not having any limits on the NDMA. To me that means zero NDMA.
Q So the fact that what the USP monitor says is that unknown impurities can be no more than

Page 130

0.1 percent, right?
A Unknown non genotoxic impurities can be around .1 percent or a little higher.
Q But what you're saying is the monograph itself is silent as to genotoxic impurities, correct?
A Their silence is because they assume zero NDMA. They assume zero genotoxic brought.
Q And that's written nowhere in the monograph itself or in any USP publication, correct?
A Exactly. Because it's not written, it means it should be nonexistent.
Q And --
A Because the RLD was nonexistent, because the Diovan and Exforge had no NDMA.
Q Are you aware of any drug manufacturer anywhere in the world that was doing nitrosamine-specific impurity testing prior to FDA's notification of the potential for nitrosamine?
A Yes, I am. I am aware.
Q In 2018?
A Yes, I am aware of a pharmaceutical company that does test for NDMA.
Q And who is that?
A Novartis, at least one which is

Page 131

Novartis.
Q How do you know -- excuse me. How do you know what test methods Novartis was using prior to June of 2018, what's your source of information?
MR. NIGH: Outside the scope.
A Prior to 2015 -- sorry, 2018, all I am aware is that Novartis discovered the NDMA in the ZHP product and it's because they were looking for it. They found it. They were testing it. They had space and they saw the impurity and identified the impurity. It takes no more than 10 minutes by running a GCMS to identify NDMA.
Q My question is what is your source of information that Novartis was doing nitrosamine testing prior to June --
A Public information.
MR. NIGH: Outside the scope.
Q Can you cite me to that public information, because I've never seen it.
MR. NIGH: Outside the scope.
A European medical authority has written about it. It was to, you know, basically -- I think that's part of EMEA in one of their reports I recall seeing it that they mentioned that Novartis saw it or maybe it was chemical engineering news, but I

Page 132

think you can Google it. You should be able to see Novartis. Just type in Novartis nitrosamine impurity. I think you will run into chemical engineering news. I might have been cited there was well.
Q Didn't you develop specialized test methods to test for nitrosamines in the latter parts of 2018 and 2019?
A I don't believe so.
MR. NIGH: Objection. Outside the scope.
A I don't believe so. I think we used a standard nitrosamine methodology.
Q Did you develop a liquid LCMS method?
A We did. We developed our own LCMS method primarily not for valsartan, but for other drugs.
Q For Zantac?
A Yes.
Q So if we look at --
A And beyond Zantac. We also tested probably 20 other drugs as well.
Q Twenty other drugs for nitrosamines?
A Yes.
Q How did you pick what 20 drugs you

Page 133

were going to test?
A We look at structural clues. You look at structural clues in a pharmaceutical molecule and you say this molecule could be prone to NDMA formation and that's called structural clues. If someone skilled in the art of chemistry looks at valsartan synthesis, there are -- it's shouting. That synthetic route is shouting that it's going to be forming a NDMA. We use those kinds of structural clues to look at other compounds to see whether they form NDMA or not.
Q What are the 20 other drugs you tested?
A I can't -- off the top of my head I can't recall.
Q Can you recall any of them?
A We looked at -- obviously we looked at nizatidine, which is a cousin of ranitidine. We looked at famotidine, which is also an anti-acid. We looked at a whole bunch of antacids, you know, and we might have looked at some over-the-counter sort of diphenyl hydramine; you know, things like that.
MR. TRISCHLER: I'm sorry. I need to take a break. I've got something I need to take

Page 134

care of. I had an appointment scheduled for 4:30 that I realize I'm going to have to cancel, so I need a couple minutes to take care of that. Sorry, Dan.

MR. NIGH: What's the problem? Let's take a ten minute break.

THE VIDEOGRAPHER: The the time is 4:24. We are going off the record.

(A recess was taken.)

(After the recess the following occurred:)

THE VIDEOGRAPHER: The time is now 1:36. We're back on the video record.

BY MR. TRISCHLER:

Q So, Doctor, you have told me that it is -- that it's your opinion that a drug company should not sell a product with any nitrosamines, correct?

A That's what I said.

Q And we talked about the fact that the regulations allow unknown impurities as high as 300,000 nanograms for a 320-milligram tablet product, you interpret that requirement that USP specification as saying it applies only to non geo toxic?

Page 135

A Genotoxic.

MR. NIGH: Form objection.

Q Right. It applies only to non genotoxic?

MR. NIGH: Form objection.

A I don't understand your question. My apologies. Could you repeat?

Q Yes, I will ask again.

A Could you ask a specific question?

Q I will ask it again. I was trying to make sure I understood your testimony. I think I do, but what you've told us is the USP specification that allows for unidentified impurities to be as high as 300,000 nanograms in a 320 milligram product only applies to non genotoxic impurities?

MR. NIGH: Form objection.

A That applies to non genotoxic impurities.

Q Right. If I misspoke, I apologize.

A Right.

Q That's what I understood, and that's because you interpret the absence of any specification in USP as a dictate or a mandate that the requirement for genotoxic impurities must be zero?

Page 136

MR. NIGH: Form objection.

A Let me explain. So requirement for genotoxic impurities are far lower than regular impurities. So you must have a lot less genotoxic impurities in your drug and the levels are listed. In the case of specifically nitrosamines and specifically NDMA, the requirements should be zero.

Q And you indicated that you were aware of at least one company prior to 2018 that was testing its product and making sure that its valsartan nitrosamine levels were zero, and that company was Novartis?

MR. NIGH: Form objection.

A As far as I know, there may be many, many more companies testing their compounds for nitrosamines, but as far as I can tell from, basically, public records, you know, NDMA -- obviously Novartis looked for NDMA. Novartis found NDMA in their API, and I can only give you my opinion that Novartis perhaps -- they buy a lot of APIs from China and India. Perhaps they look for NDMA in every API they buy.

Q And do you -- you indicated that or you offered the opinion that a drug company that sells a pharmaceutical product that contains a

Page 137

genotoxic impurity at any level or any concentration is not equivalent to the reference listed drug because the reference listed drug does not have genotoxic impurities, right?

MR. NIGH: Form objection. You could answer.

A The genotoxic drugs, you know, have limits that they need to abide by in an active pharmaceutical ingredients and there are specific numbers and the numbers, Clem, is not 300,000 parts per million. It's in the hundreds of parts per million, maybe even much less.

In the case of nitroso, nitrosamines and the n-dimethyl nitrosamine the requirements are zero because this is a genotoxic, DNA reactive, cancer-causing molecule. And furthermore, FDA says the levels should be zero because there are synthetic methodologies. In layman's terms there are recipes to make valsartan without any NDMA, so manufacturers should use that recipe. And, you know, that's my opinion and I think the levels should be zero for NDMA.

For other genotoxic compounds there are specific levels and one has to consult with ICH guidelines, ICH M7 for those levels.

Page 138

Q Okay. Well, that's fair. I'll try to confine my questions to NDMA and NDEA. Okay?
A Thank you.
Q And if I understand your opinion, what you've told us is that you're of the opinion that a generic formulation that contains NDMA or NDEA is not equivalent to Diovan or Exforge, because those reference listed drugs have zero NDMA and zero NDEA?
A The generic drugs that contain NDMA do not meet the requirement. I have not tested Diovan or I have not tested Exforge. I can only assume that they are -- they have zero NDMA because they were not recalled, so that's what I said.
Q Well, yeah, and that's what I wanted to get at in terms of trying to understand what we have here today.
The opinion that we framed earlier was -- that you intend to offer is that the generic drugs made by valsartan-containing medications made by my client and some of the other defendants for this litigation, you do not believe those drugs are equivalent to the reference listed drug, because you have assumed that the defendant's generic products contained NDMA and NDEA and you assumed that the Diovan and Exforge did not?

Page 139

MR. NIGH: Form objection.
Q Right?
A If the manufacturer does not comply with the impurity limits which is really zero, they are responsible -- and they change their procedure, they change their recipe, they change the way they make something, then they need to -- there are these alerting structures. I'm kind of giving away a lot of my opinion that will come later, which is there are alerting structures. These are clues for you. Those alerting structures were ignored and, hence, they now have to deal with NDMA and all the issues and --
Q I appreciate the sneak preview, but I honestly don't want to go there. What I just want to understand is --
A The assumption.
Q Perhaps if you will let me explain, I can ask a question that's fair and easy to understand, Doctor. I just want to make sure I understand the assumption that forms the basis for your opinion that you've offered so far in the declaration we have.
You told me that there's two core opinions. One of them is that generic drugs at issue in this

Page 140

litigation are not equivalent to the reference listed drug and you have reached that opinion based on the assumption that the reference listed drugs contain zero NDMA and zero NDEA, right?
A Mm-hmm.
Q Is that "yes"?
A Yes.
Q Okay. And one of the things that jump-started you in this arena and I presume provides you some basis for that assumption is you started working with Valisure on nitrosamine testing of valsartan before there was even litigation, right?
A So, Clem, as I have stated before, I'm not sure when we have actually officially started with Valisure. It might have been before, it might have been after, but that's what I can tell you.
Q Fair enough.
A I'm sure if Daniel would be okay, I can, you know, get that information to you.
Q Fair enough.
A But the fact remains that whether if before or after we tested your client's pills, maybe your client's pills, honestly I don't know, I'm not prepared to tell you what we have until I can give

Page 141

you reports of those, but they had high, high levels of these genotoxic compounds. And I wouldn't want anybody to be taking those drugs, you know, on long term basis because that would be -- you know, that wouldn't be good whether it would be my mother or your mother.
Q Well, my mother already passed, so I'd be happy to have her take valsartan with or without genotoxic impurities right now.
A I'm sorry to hear that.
Q But be that as it may, what I was -- and I didn't mean to misstate your testimony about the timing of your work with Valisure. You did tell me you couldn't be sure whether it was before or after the FDA involvement, so I grant you that.
A Yes.
Q But what you did talk about and what you did explain to me was that Valisure brought the issue of the potential for nitrosamines in valsartan to your attention and sort of asked you to help with the testing and evaluation, right?
A One hundred percent.
Q Okay. And so you had a chance to look at the testing that was done by Valisure early on on the valsartan and to independently validate it

Page 142

through the work of your own lab?
A Yes, we did.
Q So there is no question in your mind that the results of testing as documented by Valisure and its findings on nitrosamine contents in valsartan were accurate?
A We repeated Valisure's work according to our own procedures and we, I think we -- the result what we told Valisure was that the numbers they got was pretty much in the ballpark.
MR. TRISCHLER: Did anyone hear the doctors' answer? I saw his lips moving but didn't hear anything.
MR. NIGH: I could hear it.
A I said. Let me repeat. Can you hear me okay?
Q Now I can.
A Okay. What I said was we concurred with Valisure that they had correct nitrosamine numbers for their valsartan pills and they sent to us the same pills that they tested. I specifically warned Valisure to get it tested at a third-party lab. He called me, asked me for my advice. I said you want to get it at a third party lab to make sure. I think he was planning to do some press

Page 143

release or something, and that's what we did. And we told them yes, I think, and then he basically did something with that data. So...
Q Okay. And then you mentioned -- and so essentially I think you just answered what my question was. My question was, did you have the opportunity and did in fact independently corroborate the Valisure data as it related to valsartan nitrosamine quantification?
A That's correct. We corroborated their data.
Q And then you made mention early on -- I shouldn't say early on. You paid mention before our last break about a citizens petition and you suggested that you thought somewhere in your memory bank that Valisure might have done a citizens petition that might have related some way or somehow to valsartan. Do you remember that?
A Yes. I don't think they have.
Q I found something I want to ask you about, and Frank from my office is there.
MR. TRISCHLER: Frank, do you have the June 13, 2019, Valisure citizens petition and can you have that marked as the next numbered exhibit?
MR. STOY: Yes. I just uploaded it a

Page 144

minute ago. Bill, do you have it?
THE VIDEOGRAPHER: I have it. I am downloading it. Just give me one moment. For the record, that would be Exhibit 28 is the next one in line.
MR. TRISCHLER: Okay. Can you put up Exhibit 28, please.
Q This is on the Valisure letterhead dated June 13, 2009.
A Right.
Q Take a look at the first couple paragraphs. Does it refresh your recollection at all?
A Now I recall. I think they did file something with the FDA, but this is regarding DMF, I think.
Q You're correct that it does relate to dimethylforamide which is DMF, right?
A Dimethylformamide.
Q Formamide, okay? I'll try to do better. I didn't do very well in chemistry.
A No, no. I just get insulted when they mispronounce these chemical names, that's all. No worries.
Q I was trying to say the chemical name

Page 145

to distinguish from DMF to refer to drug --
A Yeah.
Q So dimethylformamide is subject of Exhibit 28, correct?
A Correct.
Q But there's also reference to NDEA testing was done by Valisure IN this citizens petition, correct?
A Right.
Q As I said, you saw this citizens position before.
A Right.
Q And you had validated the test results that are reported in here?
A Yes.
Q And if we look at Appendix A to the report, what we have is a summary of NDMA levels and DMF levels in valsartan tested by Valisure and confirmed by your lab?
A Did they mention our name in this report, can you Google it?
Q I don't know, but --
A If they didn't mention our name, then we didn't have anything to do with it.
Q Well, you already told me that you had

Page 146

validated their testing and corroborated the results, right?
A NDMA?
Q Right.
A NDMA, but that's if they mentioned our name, then it would be corroborated, but if they didn't mention our name, it was on their own.
Q Well, I only planned on asking you about the NDMA results reported in this.
A Please.
Q As you said at least five or six times it's called by Valisure to corroborate their data?
A Yes, but you know -- okay. Go ahead.
MR. NIGH: Form objection.
Q So if you look at the Appendix A, you're looking at the first page there. If you flip to the next page, page 10, there's more results reported. Do you see that?
A Right.
Q Page 111 there's more results reported?
A I don't think we tested that many different pills and lots for them.
Q I am only asking about what's shown here in the document. There's more testing

Page 147

reported, correct?
A Okay.
Q And the manufacturers whose product was tested was also identified in Appendix A, correct?
A Mm-hmm.
Q Is that "yes"?
A Yes.
Q Interestingly, one of the manufacturers is Novartis.
A Okay.
Q And if you look at page 12, there is results of seven test samples of Novartis product listed, correct?
A Right.
Q There was NDMA found in every single Novartis tablet, correct?
A Yes.
Q Is that correct?
A That's what you're showing me.
Q So your assumption that underlies your opinion in this case that Novartis' valsartan contained zero NDMA is not supported in the testing done by Valisure and it was validated by your lab.
MR. NIGH: Form objection.

Page 148

MR. TRISCHLER: What's that?
MR. NIGH: I just said "form objection."
MR. TRISCHLER: I meant what's that to the witness.
A And I respond to that I'm not -- I cannot confirm to you that we corroborated it everything that Valisure is presenting in this report vis-a-vis the fact that our name has not been mentioned on this citizen petition.
Typically if we do not corroborate something, they shouldn't put our name. If they are not putting our name, it means we didn't have anything to do with these.
Q Your assumption that Novartis, Exforge and Diovan formulations contained zero NDMA is not supported in the data from the citizens petition of Valisure, is it?
A Based on what Valisure is reporting to, you know, I cannot corroborate their data because we didn't do it. This is their data.
Q And their data does not support your assumption. That's all I asked.
A If their data is correct -- you know, I don't know if they are data is correct. Now

Page 149

having said that, you know, Clem, the levels that were -- the interim allowable limit of NDMA, as you know, is 96 nanograms. So under the recall, official recall and notice, anything under 96 nanograms would not be recalled. So Novartis would not be a recalled product.
Q I didn't ask you if it would be a recalled product and you were also very clear to me, Doctor, that NDMA and NDEA content in its drug product must be zero. You said that five times to me.
A That should be the goal of the manufacturers to have zero NDMA and NDEA.
Q And you criticized my clients because they had NDMA and NDEA levels higher than zero.
A They had levels of 2,000 and 3,000 nanograms.
MR. NIGH: Hold on. Hold on. Hold on. Hold on. Form objection. Does he even know your client?
MR. TRISCHLER: He's your expert. I don't know.
MR. NIGH: Okay, because we are getting way off comment on some of these topics. He has not said in terms of your client.

Page 150

MR. TRISCHLER: He just said my client.
Q Dose levels of 2,000 nanograms; is that your testimony, sir?
A I don't -- I am going on what was published by FDA. So you can Google that and see what FDA was published and double check that to see if your clients is part of that FDA recall and FDA numbers.
Q I can do a lot of things, Doctor. I spend way too much time online. What I'd like to do is ask you questions. And my question is, is it your testimony that Mylan had NDEA reported at levels of 2,000 to 3,000 nanograms in its valsartan-containing products?
MR. NIGH: This is far outside the scope of his certification and declaration at this point. I mean, you can read it. He doesn't mention a single thing about Mylan.
MR. TRISCHLER: He volunteered and I am allowed to follow that up.
MR. NIGH: No, that's not actually true. I have a lot of questions to go far outside the scope at this point, but this is way outside of the scope of his seven page declaration. Not a

Page 151

single place in here does he ever mention any of the defendants' testing levels and I think you know that. So, again, at this point we're getting way outside. I have allowed some exploration at some point, but this has no basis in his declaration at this point.
MR. TRISCHLER: I think I'm entitled to an answer to the question. You've objected. You can argue whether --
MR. NIGH: I am going to instruct him not to answer at this point. We have gone far outside the scope.
MR. TRISCHLER: Just so that I'm clear, the witness stated that my client had levels of 2,000 to 3,000 nanograms and you are not allowing me to follow up on that?
MR. NIGH: Just so you're clear, I think that question was far outside the scope in the first place. He is not here to offer an opinion as to what the levels are or your client's levels. He is not here to offer an opinion as to what any of the clients' levels are. His opinion clearly states valsartan which contaminated NDMA or NDEA, period, not about levels.
Q You told us, Doctor, generic drug

Page 152

products contain any NDMA, NDEA is not equivalent to Novartis who is the reference listed drug holder, because Novartis' levels are zero. The data from Valisure suggests that that's not true. Agreed?
A My position is that levels of NDMA and NDEA should be zero in any valsartan pills. Novartis might have some valsartan at higher level, have some NDMA in it. They might have had -- in fact, they were buying -- from my understanding they were buying ZHP's API and they were using ZHP's API, so I am not surprised they ended up with some NDMA, but prior to ZHP and any of the defendants' products Diovan and, you know, Exforge going generic, I believe they had their procedure, their process produced no NDMA.
Q Have you ever reviewed the new drug application for Diovan?
A I have reviewed a lot of documents, yes.
Q I didn't ask if you reviewed a lot of documents. Have you ever reviewed the new drug application for Diovan?
A I have reviewed it.
Q Where did you get it?
A You know, I think maybe, you know, the

Page 153

plaintiff's lawyer shared it with me.
Q I'm surprised that Novartis would turn over their proprietary documents to the plaintiff's lawyers. So your testimony is you've seen the new drug application?
A I might have seen it. I reviewed a lot of different documents.
Q Well, it was not disclosed or provided in any of the materials that were given here to me.
A I cannot recall, but I reviewed a lot of different documents relating to valsartan manufacturing; valsartan -- you know, there is a lot of public information regarding the manufacturing process.
Q Chemistry manufacturing controls submissions as part of Novartis' new drug application. It's not public information, is it?
A What is your question?
Q I just asked you that one. There is a CMC section a new drug application, public information.
A What is your question?
Q I will ask it a third time. Is the CMC section of a new drug application public information?

Page 154

A CMC section shouldn't be public information.
Q So I am trying to understand your testimony under oath that you've seen and been provided with the NDA for Diovan. Where did you get it?
A I said I have reviewed. I didn't say I've seen it. I said I have reviewed a lot of documents, you know, from different manufacturers, perhaps including Novartis' procedures, but Novartis' procedures and chemical manufacturing procedures has been disclosed in their patents. It's been published. There's plenty of literature on it.
Q So if I hear what you're saying now and if we're looking for honest, forthright testimony, it sounds like you don't know whether you've seen the NDA for Diovan, correct?
MR. NIGH: Form objection.
A I don't know if I've seen it.
Q All right. In your career, sir, have you ever prepared an abbreviated new drug application seeking to obtain FDA approval to market any generic equivalent drug product?
A In my career I have been involved in

Page 155

many IND filings, CMC sections of IND, CMC sections of NDA, ANDA for my clients, not specifically for any of my own specific products.
Q My question was have you ever been involved in preparing --
A Yes, I have.
MR. NIGH: Hold on. Dr. Najafi. Wait until he finishes his question.
A Sorry.
MR. NIGH: And then answer. We're getting --
MR. TRISCHLER: Sorry, Dan.
Q What abbreviated drug applications did you prepare and submit to the FDA?
A Confidential.
Q For what drugs?
A For drugs that -- from our clients' drugs.
Q Tell me the names of the drugs. The active pharmaceutical ingredients are not confidential.
A I can not recall right now. Also, it's client-specific and a lot of our clients don't want to have their names disclosed.
Q I haven't asked your client's names.

Page 156

A I know.
Q Sitting here today providing -- let me finish before you start.
Sitting here today providing testimony under oath, you can't name one drug product where you were involved in submitting the abbreviated new drug applications for its generic formulation, right?
A I cannot recall.
Q Have you ever worked in regulatory affairs for a generic drug manufacturer?
A No.
Q Have you ever --
A I have not worked in regulatory affairs for any generic manufacturers.
Q Have you ever worked or been employed by the FDA?
A I have never been employed by the FDA.
Q Have you ever -- are you familiar with the Center for Drug Evaluation and Research, CDER?
A I have attended many meetings at CDER.
Q Have you ever worked with CDER where you've had responsibility for evaluating new drug or new drug applications?
A I have not been involved with CDER. You should restate your question.

Page 157

Q I should or you need me to?
A Please restate your question.
Q Have you ever worked with CDER where you had responsibility for evaluating new drug or abbreviated new drug applications?
A I have not worked with CDER in evaluating any new drug application.
Q Have you ever been retained as a consultant by FDA office of generic drugs to assist in evaluating any portion of an abbreviated new drug application?
A I have not been involved in generic drug division of the FDA.
Q And I think it's Section 4 of your report -- your declaration you describe FDA expectations and requirements for generic drug manufacturers. Do you recall that?
A Could you show it to me?
Q Sure.
A Put it on the screen.
MR. TRISCHLER: It's Exhibit 1. Can you put it up, please.
A Highlight it.
Q Can you flip through it? I think it's section 4. I think it starts on page 5, maybe, if I

Page 158

recall correctly. There we go. Do you see that?
A Yes.
Q And as I was saying, this is the section of your report where I think you proceed to describe what you consider to be the expectations or some of the expectations and requirements for a generic drug manufacturer, right?
A Mm-hmm.
Q Is that "yes"?
A Yes.
Q The fact of the matter is, though, Doctor, that you're never had personal responsibility for synthesizing API that was used for generic drug formulation, correct?
A I have not had responsibility in synthesizing an API for a generic drug manufacturer, but I have been involved in, you know, drug development and I've been involved with lots of FDA-related activities and the spirit of what I have put in is if and when you change the chemical process, if you make lasagna by following step one, step two, step three, and if you change that and you create your own recipe, you have responsibility to do proper due diligence to look at structural molecules that give you structural clue to

Page 159

protection problem and you need to disclose that to the FDA and you need to do proper due diligence and effectively look for those, you know, potential problem and look for genotoxic compounds and report it.
Q Have you ever developed a synthetic process used for the API of a generic drug formulation?
A I have developed synthetic process of hundreds of molecules in my time and I continue to develop processes for hundreds of molecules, but not for a generic drug, but I can assure you I understand the synthesis synthetic procedure of valsartan.
Q Have you ever had oversight responsibility for manufacturing a generic drug product?
A No. I have not had oversight responsibilities for a synthesis of a generic drug product or drug substance, but I've had manufacturing responsibilities for lots of synthetic molecules in large scale at my previous company, Aldridge Chemical, at Rhone-Poulence Pharmaceuticals, et cetera, and NovaBay.
Q Have you ever prepared a drug master

Page 160

file in connection with an API for a generic drug?
A Not personally.
Q In the notes of deposition that brought us here today, I asked you to provide certain materials to me at the time of the deposition. One of the things I asked for were any and all papers that you prepared on the topic of drug safety and cancer risk. Do you remember seeing that request in the notice?
A Yes, I have.
Q I did not receive any papers or publications on those topics, so I have to assume that you have never published on those issues. Would that be a fair assumption on my part?
A I have not published on anything, any genotoxic compound, nitrosamines except the citizen petition which we filed with the FDA regarding nitrosamine which FDA corroborated 100 percent, and I've also presented at a generic manufacturing symposium where my audience was a whole huge number of generic manufacturing people.
Q I appreciate that, but my question was a little broader than that. I had asked for all papers and publications prepared on the broader topic of drug safety and cancer risk. Have you ever

Page 161

published on those topics?
A I haven't published on those topics and what I can -- you know, there are lot of publications. That's really a toxicologist and epidemiologist sort of activity. I rely on them.
Q And what you were answering on the topic of nitrosamines what you told me is that you've not submitted any peer-reviewed publications on the issue of nitrosamines and drug products, correct?
A So what's your definition of peer reviewed?
Q My definition of peer review would be a publication in a scientific journal that is reviewed by scientists in the field for accuracy, quality and reliability of methods prior to the time that it's published.
A Our citizen physician, my citizen petition for ranitidine Zantac meets those criterias, so under that circumstance it is peer reviewed.
Q So you consider a citizens petition to be a peer-reviewed publication?
A Absolutely.
Q Who can submit a citizens petition?

Page 162

A Anybody can submit a citizen petition.
Q If I sent a citizens petition saying Dr. Najafi's declaration in this case is unreliable, has that been peer reviewed?
A You can certainly do that and it will be peer reviewed by FDA scientists and they will then respond to you that Clem, you're wrong.
Q In formulating the opinions that are contained in this declaration that we're looking at now, did you review any internal Mylan documents?
A In formulating this last declaration, I don't believe so.
Q Did you review by ZHP documents?
A I have reviewed both Mylan and ZHP documents months ago but not in formulating this declaration.
Q And if I ask the same question for the other manufacturer defendants to this litigation: Teva, Aurobindo, Hetero, Torrent; have you reviewed any of their documents?
A I have reviewed. I've spent hours and hours looking at their manufacturing issues, looking at their, you know, all of that, but not for this, you know, putting this declaration together.
Q So in terms of those two core opinions

Page 163

we talked about, you don't plan to -- you're not relying upon and did not consider any of the -- any internal documents from any of the manufacturers?
A I did not, no.
Q I asked you before if you reviewed the new drug application for Diovan and you said you could not. Just for completeness sake, do you know if you ever reviewed the new drug application for Exforge or Exforge HCT?
A I cannot recall. I believe I've reviewed a lot of the defendants' material. I might have reviewed some of the publicly available information on the work Ciba-Geigy did which led to Diovan.
I've looked at their patents. I've looked at their procedures, their recipes, their synthesis, published data, a lot of that. I have looked at a lot of documents over the last year and a half or so.
MR. TRISCHLER: Let's take a break, please. I want to look at some notes and see what I want to do next.
MR. NIGH: Take a ten minute break?
MR. TRISCHLER: Sure.
THE VIDEOGRAPHER: The time is 2:22. This concludes Media No. 4.

Page 164

(A recess was taken.)
(After the recess the following occurred:)
THE VIDEOGRAPHER: The time is now 2:48. This begins Media unit 5. You may proceed.
BY MR. TRISCHLER:
Q Doctor, I just have a few other things I want to cover with you. One of the documents that was in your file that I was provided with was a chart entitled "valsartan products not currently recalled." Are you familiar with that chart?
A Would you bring it up so we can be looking at the same thing?
Q Sure.
MR. TRISCHLER: Frank, are you able to -- it was not in the group of exhibits that I premarked. Are you able to pull it up, Frank, and get it in front of the witness?
MR. STOY: Yes. Let me try to find it here. I am going to attempt to share my screen. Is this the document?
MR. TRISCHLER: Yes, that's it. Thank you, Frank. I guess we will have this marked as an exhibit and sent to the reporter through the chart, but whatever the next numbered exhibit is.

Page 165

THE VIDEOGRAPHER: That will be 29.
MR. TRISCHLER: Thank you.
BY MR. TRISCHLER:
Q Doctor, can you see this Exhibit 29?
A It is very tiny. Yes, I do.
Q It's a 15 page document. At the top it says "valsartan products not currently recalled" dated September 21, 2015, and it was provided to me by your counsel as part of your file. Do you recall that?
A Yes.
Q And if I understand correctly this would be a list of valsartan products, marketed and sold in the United States that were not subject to any recall at least as of September 2018, right?
A I believe so.
Q And you had mentioned earlier that under the valsartan recalls, products were recalled if they had NDMA content above 96 nanograms per milliliter, right?
MR. NIGH: Objection. Go ahead.
Q You can answer.
A Ninety-six nanograms dosage you end up consuming per day.
Q The limit for NDEA, there was a

Page 166

separate limit for NDEA, right?
A I think NDEA was far lower, maybe 12 or 20, something like that.
Q Does 26.5 sound right?
A Yes.
Q And so if valsartan products were tested and the limits observed were above those levels of 96 nanograms for NDMA and 26.5 nanograms for NDEA, they were recalled, is that your understanding?
A That's my understanding.
Q And so this list would be a list of products that had NDEA content of either zero or less than 96 or somewhere in between?
A Right.
Q And these would be -- this list that we will mark as Exhibit 29 is a list of product that would have been tested and had NDEA content of either zero or 26.5 or something in between.
A Right.
Q To your knowledge, have you independently tested any of these valsartan-containing medications that appear on this Exhibit 29?
A I have not. I'm not prepared in this

Page 167

meeting to to take a look at these and compare it with what we have or have not listed, because I'm just -- I don't have the documentations in front of me to tell you what got tested and what didn't.
Q Okay, but based on what we know right now, all of the drug products listed on Exhibit 29 may very well have had some NDMA or NDEA in the product, it was simply below the limit established by FDA?
A That's what FDA has obviously done. They have made those determinations based on this interim level, interim level which is 96 or 20-something nanograms of NDEA.
Q So as far as we know, every drug listed on Exhibit 29 had some NDMA or NDEA in it, right?
A As far as I can tell you, I have no knowledge of what the exact numbers of NDMA or NDEA is in any of these products. All I can attest to is that they were not recalled by the FDA.
Q And so you cannot rule out the possibility that every drug listed on Exhibit 29 had some NDMA or NDEA?
A I cannot rule out. Let me just restate my position. I believe no NDMA or NDEA

Page 168

should be allowed in any valsartan product, period. Zero. So if they contain NDMA and NDEA and FDA is allowing it above certain limit, that's FDA's prerogative, but in my expert opinion, no NDMA or NDEA should be allowed.
I am not a toxicologist, but I know something about the chemistry of NDMA and the fact that it comes a methylating agent, and methylating agents are a fantastic cancer causing agent.
MR. NIGH: Dr. Najafi, make sure you let him finish his question before you answer.
THE WITNESS: My apologies.
Q The limits established by FDA that you've referenced --
A Right.
Q -- 96 nanograms per millimeter for NDMA, that limit remains in effect to this day, does it not?
MR. NIGH: Object to form.
A As far as I know, FDA currently is accepting 96 nanograms as an interim sort of level, but their goal is going to be zero and their goal is going to be basically FDA -- I'm reading from FDA's guidance. It says FDA advises that nitrosamines should be absent, not detectable for ARBs, API or

Page 169

ARB product period, stop. It's been cited in my FDA general advice document which is actually cited in my report.
Q All I asked you was that the limit of permissible NDMA content of 96 nanograms per milliliter remains in effect to this day.
A As far as I know, 96 nanograms remains in effect and is acceptable today, but may not be acceptable tomorrow.
Q And the 26.5 nanograms limit for NDEA remains in effect to this day?
A As far as I can tell, that remains as an interim acceptable level today but, again, their guidance says they are going to go to zero. So I am answering your question.
MR. TRISCHLER: All right. I have no further questions of the witness at this time. I do think that there are documents that we have requested that have been -- excuse me, documents that have been identified worked on by this witness that were identified during the course of this deposition that are relevant to the witness that have been disclosed in this case and that the witness has been offered.
I am going to reserve the right to

Page 170

bring a motion on that issue to obtain those documents and those records and to redepose the witness on those issues, but for now I don't have any further questions, although I believe there may be a few other people on my side that have some followup.

MR. NIGH: Mr. Trischler, I am going to put my position briefly. I think at this point we've gone over four hours of record time which is, in many of these questions, have been far outside of the scope. And the vast majority of documents, if there are any, we presented those objections 48 hours ago and do not believe there is a basis to come back for this deposition.

In addition, I'm surprised that it's even gone four hours, but it sounds like it's going to go even further and so I don't even know if there will be any time at the end of this. And to the extent that there is an argument being raised of missing documents, really, the timing here has just gone far longer than we think was necessary. That's my position.

CROSS-EXAMINATION

BY MR. GISLESON:

Q Good afternoon, Doctor. My name is John Gisleson and I represent Aurobindo.

MR. GISLESON: If we could go back please, Bill, and pull up Exhibit 17, which is the valsartan USP monograph.

Q So, Doctor, in your career to what extent have you utilized USP monographs in your work?

A We use it almost every day, every week at Emery Pharma to effectively follow, you know, and release drug product and drug substance at Emery.

Q To your knowledge are the USP monographs utilized in connection with manufacturing?

A USP monographs are utilized in connection with manufacturing, yes.

Q Do you know whether the FDA relies at all on USP monographs?

A To some extent they do. FDA and USP have sort of a tangential relationship with the USP. USP is an independent company and it was formed 200 years ago for the purpose of, essentially, standardizing our drug supplies and trying to develop a standardized quality system for the drug on the market.

Q Do you have an understanding as to how FDA utilizes USP monographs?

A Can you be specific? You know, what do you mean by to what extent FDA utilizes?

Q Do you have an understanding as to how FDA utilizes USP monographs?

MR. NIGH: Objection. Form.

A USP primarily works with the sponsor of the innovators to get the -- you know, basically to get the drug, the generic drugs, you know, effectively easing the generic drug availability.

So, for example USP toward the end of the drug patent, USP contacts the brand and says "share with me your protocol. Share with me your standard. Share with me your impurities," and the drug -- the brand usually does that. If they don't do it, USP develops its own standards and then everybody has to meet that minimum standard.

Q In your experience, are the USP standards reliable for manufacturers?

MR. NIGH: Form objection.

A Could you repeat your question?

Q Sure. In your experience, are USP monographs accurate in their prescription of the drug products addressed in the monographs?

MR. NIGH: Form objection.

A In terms of reliability, it's a minimum standard that you have to meet, but we often go above and beyond USP.

Q And in your experience, are the USP monographs reliable in terms of the accuracy of the information that they contain?

MR. NIGH: Objection.

A In my experience, USP monograph is the starting point for, you know, for basically looking at the impurity profile.

Q And if we look at Exhibit 17, does this identify specific impurities that have been found in the valsartan product?

A They do.

Q What are the specific impurities that are identified there?

A There are a couple of impurities listed; impurity A, impurity B, but in fact there are more impurities.

Q Do you have an understanding why, then, the USP monograph didn't identify all impurities?

MR. NIGH: Form objection.

A We often find other impurities and we bring it to the attention of the sponsor and show

Page 174

them that these impurities need to be identified or if the levels are -- meet certain standards, they need to be identified or they need to be, you know, purified, tested, quantified. Really, there are different standards, but no, USP -- how can I say it, it's really just -- it's really an entry point, you know. It's really a starting point. It's a guidance.

Q In your experience are USP monographs updated from time to time?

A I believe they are.

Q In your experience, when USP monographs are updated, would they also include additional impurities that weren't previously known?

A They often do, but they are very slow in doing that. A company such as ours would actually need to contact USP and say, hey, we actually found additional impurities, you know, you should list that and it might take them a couple of years to bring that up and do their own testing and corroborate and all of that and then it might get into that, you know it might get into sort of USP monograph.

Q And in your experience it's good practice when new impurities are identified to

Page 175

report those impurities to the FDA; is that right?

A Absolutely. Reporting them to USP is a good practice. If it's a genotoxic compound, I think you want to make an more urgent case reporting it to the manufacturer, reporting it to the USP, reporting it to the FDA in the case of, for example, sartans or ranitidine, Zantac and others.

Q Does the -- and we'll look at Exhibit 17 specifically. Does this USP monograph identify how to test for impurities?

A This USP monograph does provide you with a basic methodology to identify some of the impurities.

Q What is the methodology that's identified on this USP monograph?

A Thank on hang on a second. There is -- to identify impurities you have to go through set up either HPLC or gas chromatography, various instrumentation and set it up, set up the instrument and run it according to the basic principle that USP lays down.

Q What are the specific tests or tests that are identified in this USP monograph for testing for the presence of impurities?

A So they use -- basically to assess

Page 176

impurity profile, they are using chromatographic technique. Chromatographic technique means -- meaning in this case high pressure liquid chromatography and that's it.

Q If we look under the impurities section on this first page, there's a reference to chromatographic system, see chromatography 621 system suitability and then it has mode LC detector UV 230 NM.

So what is the information that provides to a manufacturer as to how to test for an impurity?

A You're getting fairly technical here. I don't know whether this is useful for this conversation, but the HPLC is an instrument that there are pumps attached to it. The pumps are pushing. There are two pumps pushing some vents into a column. There's solvent A, solvent B, and depending on what's in the solvent A and B, the column gets conditioned so that the column is a stationery phase. And so the separation happens through the HPLC column and then it goes through a detector and then that detector would be, you know, UV detector. It could be, you know, CHAD detector which stands for charge aerosol detector. It could be ELT detector. It could be a mass spec detector.

Page 177

So it goes through the detector and comes out and out of that detector. So any UV active compound gets detected. So in this case they are looking at for UV active compound.

Q How much -- I'm sorry. Continue. Are nitrosamines UV active compounds?

A Nitrosamines are not UV active compounds. So they become invisible, so UV.

Q Using the chromatographic system with liquid chromatography and a UV detector, in your experience is that capable of identifying nitrosamines?

A In my experience you have detectors are not capable of detecting nitrosamines.

Q Does this USP monograph identify that a manufacturer should use gas chromatography, mass spectormetry to test for the presence of nitrosamine impurities?

MR. NIGH: Form objection.

A So this specific monograph does not provide you with the, you know, HPLC mass spec detector detection.

However, you know, the chemist and the synthetic chemist who is involved with the synthesis of the drug should consider, you know, methods that

Page 178

do not -- that can potentially show the none UV active compound such as nitrosamine and use of mass spec. For example, HPLC connected to a mass spec or GC connected to a mass spec, that's been around since I was an undergraduate in 1979.

Q How many to your knowledge -- strike that.

What drugs prior to June 2018 were found to contain nitrosamine impurities?

MR. NIGH: Form objection.

A To my knowledge, you know, the drugs that contained nitrosamine impurities, perhaps not known to me. That doesn't mean that it exists, but nitrosamines have been around since 1970s and knowledge of NDMA has been around since 1970s and WHO has been warning drug companies to look for NDMA through various guidances regarding nitrosamine.

And ICH M7 guidelines specifically mentions nitrosamine as the drug of concern as they have -- as the impurities of concerns as a mutagen of concerns. So just because they haven't been shown before 2018 doesn't, you know, basically give these guys a pass.

Q You said that you were familiar with current good manufacturing practices. Are you aware of any current good manufacturing practice that

Page 179

existed in or before June 2018 that required a manufacturer to test for nitrosamine impurities in pharmaceutical products?

A In current and good manufacturing practices really refers to using the latest technology and in looking for impurities, making sure your drug is safe.

And this is exactly to the point I was trying to make earlier, that basically the USP monograph is really just opens the door to you. So this is a common mistake and I also mention that in my presentation to this symposium that I was presenting regarding which is online, actually. You know, companies need to be looking for structures of concern which is mentioned in ICH M7, and those structures of concern should actually give you sort of a window toward compounds you should be looking for.

Q Can you identify any publication that was issued before June 2018 that advised pharmaceutical manufacturers that testing for nitrosamines was part of current good manufacturing practices?

MR. NIGH: Form objection.

A I can refer you to international

Page 180

committee to -- IRAC. It's a part of WHO that specifically warns the manufacturers to look for nitrosamines and there is a specific test that they ask a lot of manufacturers to do which is called -- basically it's called NAP testing, N-A-P testing, which in fact they encourage manufacturers to test their compounds to see if it's prone to developing nitrosamine. And you can look that up under NAP testing or basically WHO testing for nitrosamine and -- nitrosamine and NDMA.

Just one second. I actually have somebody here. I have to give them the key to my car.

MR. NIGH: Let's take a quick break.

MR. GISLESON: Okay.

THE VIDEOGRAPHER: Time is 3:18. We are going off the video record.

(A recess was taken.)

(After the recess the following occurred:)

THE VIDEOGRAPHER: The time is 3:18. We are back on the video record.

BY MR. GISLESON:

Q Did the FDA ever issue any guidance like what you have just described from that international organization?

Page 181

A Has FDA ever issued any guidance regarding NDMA or nitrosamine?

Q Similar to the international guidance you just identified.

A Post 2018 or pre 2018?

Q Pre 2018.

A I don't know, honestly.

Q You received an envelope and I think you started to open it earlier that contained some documents that we sent to you.

A Right.

MR. GISLESON: Bill, it's the document behind Tab 6. It's a USP monograph, this one for valsartan and --

THE WITNESS: Should I open it?

MR. GISLESON: Please.

THE VIDEOGRAPHER: For the record, it would be marked as Exhibit 30.

Q Doctor, it's behind Tab 6.

MR. NIGH: Mr. Gisleson, how am I getting a copy of this document?

MR. GISLESON: It's in the Exhibit File Share, Paul.

MR. NIGH: Okay. Okay. Tab 6. I see it now.

Page 182

Q Have you, Doctor, reviewed the USP monographs for all the different valsartan products that are at issue in this lawsuit?
A I have reviewed a number of them, yes.
Q And have you also reviewed the USP monograph for the valsartan hydrochlorothiazide tablets?
A Yes, I believe so.
Q Looking at Exhibit 30, is it correct that you have reviewed this USP monograph previously?
A This is --
Q Tab 6.
A Tab 6? Okay. Okay. I need a refresher. Just give me a second.
Q No problem.
A Okay. I scanned through it. Go ahead with your question.
Q So this USP monograph became effective as of May 1, 2015; is that right?
A Okay.
Q Looking at the upper left-hand corner of the first page.
A Uh-huh.
Q Is that correct?

Page 183

A Yes, May 2015.
Q And then if you can go to the section, please, on impurities which I believe is the third or actually the fifth page.
A Okay. Yes. I'm on it.
Q Thank you. Does this identify specific impurities that had been identified in the valsartan and hydrochlorothiazide tablets?
A It looks like it, yeah.
Q And what were the specific impurities that were identified?
A There is hydrochlorothiazide, benzothiadiazine related compound A. There's hydrochlorothiazide RS; there's USP valsartan RS; there's USP valsartan related compound and so forth.
Q To your knowledge are there any health effects or health hazard associated with those impurities?
MR. NIGH: Form objection.
A I don't know.
Q Then this also shows that there are acceptance criteria for those impurities that allow them to be present in the finished drug product at certainly no more than percentages; is that correct?
A Right.

Page 184

Q When it says in here that NMT 0.2 percent of any other impurity excluding valsartan-related compound A, does that include unidentified impurities?
MR. NIGH: Form objection.
Q Let me rephrase the question. Do you have an understanding of what's meant by not more than 0.2 percent of any other impurity?
A Yes.
Q What does that mean?
A So it means there are other unidentified impurities potentially that should not be more than .2 percent, not more than .2 percent in the chromatogram.
Q Does this monograph identified the testing procedure that a manufacturer should use to identify any impurities for this valsartan-containing drug?
A So, basically, again, it goes back to this question the whole concept that I tried to explain with Clem. There are impurities that -- you could have up to maybe a hundred different impurities, John, in valsartan in this chromatogram, hundred little peaks, right?
You can't identify. You can't tell which one

Page 185

is which. You just go after picking up a few of them, you know, and USP effectively provides those impurities as reference standards and so forth, but it's really the duty of the manufacturer to look at the drug synthesis and identify and look for their structural entities of concern.
You know, for example, when I look at a molecule, John, when I look at c double bond o, c carbon and chlorine, I know this chloromethyl ketone is like a tear gas. It's going to burn your eyes. If I see a molecule that has nitrite in it, I'm going to say "Oh, shit. This is going to --" pardon my language -- "this is going to be created nitrosamine."
So when you look at these types of -- you know, this is like the recipe that USP gives you is more or less like a TikTok video cookbook. Have you seen these TikTok videos that give you direction on how to make, you know, a certain dish? This is a TikTok video. So what you need to do is you need to do your own due diligence. You can talk to any chemist. At my company or at any other company, they tell you this is just an entry level stuff.
So it's the duty of the organic chemist at the company, synthetic organic chemist to say there are

Page 186

structural concerns in my recipe and I am worried about this impurity; therefore, look into it, okay. So, this is very little and you cannot just say here is TikTok video, you know, are you going to be able to do this. You can't. And in fact every -- this is just a starting point.

Q So when this refers to acceptance criteria no more than 0.2 percent of any other impurity, the manufacturer is to add up the different unidentified impurities to determine whether the total amount exceeds 0.2 percent?

A It means you could have lots of little impurities as long as they are not over a certain level, as long as they are not over .2 or .1 percent, but you also need to consider if these impurities are growing or not as a function of time.

Often we get a call from a frantic manufacturer that says my drug is on the market and we have -- we got report from our retained testing that our drug is producing an impurity and we need to figure out what that impurity is, and they tell us drop everything, work on this, figure out what this impurity is, you know, and we've been doing -- we have done this.

So this is -- just to show me a few impurities

Page 187

here, I can assure you if you look at some of the chromatograms of valsartan or this, the one that you're showing me, there are going to be many, many, many different impurities in the chromatogram.

Q What is the testing method in this monograph that a manufacturer should use to determine whether there are any impurities?

A They need to follow current good manufacturing practices and the current, you know has -- you know, it means you gotta LCMS. HPLC alone, it is a 1960's technology and unfortunately FDA has been very lax about it and we've had discussions with them. And companies are saying we can't afford LCMS. Are you kidding me?

Q What is the testing method identified in this specific monograph for how a manufacturer should test for impurities?

A The testing method they are identifying is HPLC with UV detector.

Q Is that shown on the prior page?

A Yeah.

Q Under chromatographic system?

A Yes.

Q Can you go to the prior page, please?

A Yeah, I am looking at it. Yeah. It's

Page 188

UV.

Q And it says chromatographic system?

A Yes.

Q See chromatography 621 system suitability mode LC detector UV.

A You see the detector is UV, which means it's ultra violet detector. So in my opinion, USP is not following CGMP. USP is behind time and these companies are hiding behind USP and I think they are violating FDA's current good manufacturing practices. And I have mentioned this to, you know, drug manufacturers, the generic people as well and they agree. I've had conversations with many of them.

Q The test that's identified here, the chromatographic system using the LC mode with a UV detector, that test is the starting point, you said, for what a manufacturer should do to test for impurities?

A Exactly.

Q And that test does not identify nitrosamine impurities, does it?

A No, it doesn't. You could have a lot of nitrosamine in this compound and this LC test will not show it. It will be invisible.

Page 189

Q So it's your opinion, as you said, that none of the defendants' valsartan products should have contained any NDMA or any NDEA; is it correct that you believe FDA is wrong in permitting the defendants' valsartan products to be sold so long as they are -- they have less than 96 nanograms of NDMA or 26.5 nanograms of NDEA?

MR. NIGH: Form objection.

A John, I cannot comment for FDA, but I have stated this in our previous conversations as well. I believe the levels of NDMA and NDEA should be zero. These are mutagenic DNA reactive molecules that knocks the hell out of your DNA, and in fact the NDMA is used to create cancer in laboratory animals.

Q So your opinion, then, directly contradicts the FDA's determination that patients may use the defendants valsartan products so long as they contain less than either 96 nanograms of NDMA or 26.5 nanograms of NDEA, correct?

MR. NIGH: Form objection.

A I'm going to reiterate what I said, John. I believe in zero NDMA and NDEA. I think FDA's thinking is also zero NDMA, NDEA. In my opinion, perhaps maybe it's because it's political,

Page 190

I don't know, but you're asking my opinion. I cannot speak on behalf of FDA. I told you what I think.

Q All right. Your opinion contradicts the FDA's determination that these valsartan products can be sold to and consumed by patients so long as the nitrosamine levels are less than the accepted intake levels identified by the FDA, correct?

MR. NIGH: Form objection. Hold on. Form objection. Mischaracterizes testimony. It's been asked and answered multiple times.

MR. GISLESON: It's been asked. It hasn't been answered.

MR. NIGH: It has been answered. It's just not the way you want it answered.

Q Your opinion directly contradicts what the FDA has said; namely, the defendant's products can be sold to and consumed by patients so long as the nitrosamine levels are less than the FDA's determined acceptable intake levels or limits?

A So --

MR. NIGH: Form objection. Asked and answered. Mischaracterizes testimony.

A John, I have already mentioned what's

Page 191

my opinion. I have also and FDA has also made its ruling. FDA is saying 96 nanograms is the interim level, but FDA in their most recent filing which is -- I'd like to quote you my -- the FDA guidance which is called FDA general advice and I'd like to actually make -- put that as part of the record if you could -- I don't know. It's page 1 and it's paragraph number -- it's page 1, paragraph 2 of background. I'd like to make that as part of the record and I'd like to read it that to you.

It says, "Due to their known potent carcinogenic effect and because it is feasible to limit these impurities," because it's feasible to limit these impurities "by taking reasonable steps," meaning chemical synthesis, chemical synthetic steps "to prevent or eliminate their presence, FDA has determined that there is no acceptable specification for nitrosamine in ARBs, API or drug product." Period. Full stop.

This is FDA. If you want to misquote me, you can go ahead and do that but, please, when you do, make sure you put this next to it. Therefore, FDA goes on and says, "FDA advises that nitrosamines should be absent in practices; i.e. not detectable as described below from ARB API and API brought

Page 192

product," should be absent.

This is the key thing. As an initial measure, FDA published levels of impurity exceeding these interim levels recommended for recall before the market. So they said they recommended anything above certain level to be recalled, but their goal is zero. Zero. I hope I've answered the question.

Q Doctor, what's the date of the document you just read from?

A The date of this document? Let me look it up. It's part of the submission of the -- I don't know. I think that's for you guys to figure out. This was -- there is no date on it.

Q Can you show us the first page of the document, please, on the camera so we can see what it says? It looks like it's a letter from the Department of Health and Services.

A Is this part of the record? I think that was submitted.

Q No, because I didn't offer it and I've never seen it before.

A It was part of my testimony. It's there.

Q Even with the presence of NDMA or NDEA, do the defendant's valsartan products still

Page 193

lower blood pressure in adults and children who still use the products?

MR. NIGH: Form objection.

A John, you want my honest opinion? I don't know. I don't know, because there is no doubt -- I have no doubt that there is valsartan molecule there, but I have no idea what the interaction of NDMA, NDEA at those high levels could be, because I consider NDMA and NDEA as an active compound.

A lot of the impurities that you saw in the USP monogram, a lot of the excipients: The sugar, the magnesium citrate and various just binding agent that makes them feel inactive, nitrosamines are extremely active and so I don't know whether actually they will help or hurt or they will cause certain -- you know, bind something to some receptors.

I'm not a toxicologist. I'm not a physician to know, but that's for another expert to comment.

Q Have you done any analysis as part of your work in this case to determine whether NDMA or NDEA interferes with the chemical ability of valsartan to perform its intended purpose of lowering blood pressure and of reducing hospitalization for heart failure?

Page 194

A We have not done any testing that shows that in DNA inhibits the effectiveness of valsartan or promotes its effectiveness of valsartan or any of that. We have not done any of those tests.

Q And you also didn't do that testing for NDEA to determine whether it had such an effect, correct?

A We have not done any testing to show whether NDEA promotes the pharmaco dynamics of the drug or actually inhibits the pharmaco dynamics of the drug. You could actually increase the activity of the valsartan or reduce its activity, any of those things. I don't know. We haven't done any testing. Nobody has asked us. Plaintiffs' lawyers have not asked us to do any of that.

Q Nor have you used your knowledge and experience simply to analyze without testing whether NDMA or NDEA interferes with the ability of valsartan to function as intended according to the label?

A We have not done any of those testings and it's not part of our plan to do any of those testings.

Q Are you familiar with the phrase

Page 195

compendial standards?

A Yes, I am.

Q To what does that refer?

A Compendial standards are standards, basically official quality standards used for drugs sold and reference standards.

Q Are those the standards in the USP monographs?

A Yes.

Q You said that you've been involved with the preparation and submission of ANDAs, A-N-D-A-S; is that correct?

A Mm-hmm.

Q Yes?

A Yes.

Q Have you ever created a connection with a ANDA risk assessment?

A Have I created a risk assessment document?

Q Yes.

A We've done many risk assessments in connection with and ANDA, in connection with NDA, new drug application; we have developed a risk assessment for any of our release testing. We do this on routine basis.

Page 196

Q In your experience do risk assessments that are submitted in connection with an ANDA to the FDA address the presence of impurities?

A Sometimes. Sometimes they do, sometimes they don't. It really depends on how good at CMC a person a company has and how good a chemist they have and how they can -- if they, for example, you have a drug that all of a sudden develops odor, you know, sitting and it's causing odor or the drug is changing, you've got to do risk assessment and you need to submit it to the FDA.

And those risk assessments also, I would call them a root cause analysis. They would need to go to -- they could be very narrow. They could be very extensive. It really depends on the company and it depends on the team that's involved.

Q In your experience, does the drug manufacturer identify the tests that the manufacturer performed to evaluate risks associated with the drug product at issue in the ANDA?

A Could you repeat your question? I kind of lost my train of thought.

Q Sure. Does the drug manufacturer have to identify in the risk assessment the specific tests it performed in developing the assessment?

Page 197

A Yeah. They should. They should. For example, at any time you change the chemical process, you change your synthetic route, any time you change the cap of -- let's say you go from glass to plastic, you need to do risk assessment; how is that going to impact your drug.

You go from, you know, a prefilled syringe to another prefilled syringe, you need to do risk assessment. In this case, you know, we're getting into the really nitty gritty of sort of liability issues, Daniel but, you know, in this case they should have -- they changed the chemical process. They should have done what I call the structural sort of drugs, they should look at the structural concerned molecule and they should look at those structural concerns and say what are the chances of something going wrong with this and then do a proper risk analysis and not just brush it under the table or say this is just minor thing and go on with it.

You know, using, for example, John, sodium nitrite, in the original process they didn't use sodium nitrite, whereas in the, you know, in the defendant's process almost invariably everybody used sodium nitrite. Sodium nitrate is the same molecule that you find in a lot of, you know -- it's a

Page 198

nitrated food; you know. You get potential formation of NDMA. That's where nitrosamine comes from, and sodium nitrite are known to cause nitrosamine and NDMA. So that's where the risk analysis went wrong.

MR. NIGH: I need to interject something at this time. As you can see, there is a seven page declaration. He has not gone into detail in terms of his liability opinions and I would warn counsel at this point if we are going into liability opinions, we're not going to cover this ground again. There's not going to be a second bite of the apple at those topics.

MR. GISLESON: I am not going into liability issues at all. I am specifically addressing his point he's made a couple of times, that in his view the defendants didn't do what they should have done in connection with evaluating or testing for NDMA and NDEA, and so I'm following up on that.

MR. NIGH: Yeah. That's in large part because of the questions that occurred earlier that also touched upon liability. So to the extent we are going to continue further and follow up on liability, defense counsel could do so at their own closing.

Page 199

MR. TRISCHLER: And as you are aware, the witness just went well beyond the scope of my question to volunteer a bunch of information, which is why I am also following up on it.

Q The bottom line, in your experience the ability to instruct the manufacturer to perform additional tests if the FDA believes the risk assessment did not appropriately evaluate certain risks; is that true?

MR. NIGH: Again, this is clearly liability. The more you want to follow down that tunnel, the more you are following up on liability opinions. This is far outside the scope of his declaration.

A Let's talk about NDMA levels, John.

MR. NIGH: Just because he voluntarily gives information in response to one of your questions that's also a liability question and continue to go down that tunnel doesn't mean that defense counsel is not opening the door to this questioning, and they are not going to get a second bite at the apple.

BY MR. GISLESON:

Q The FDA can direct additional tests if it believes it appropriate when it evaluates a risk assessment in an ANDA, correct?

MR. NIGH: Form objection.

A The FDA can ask for additional tests if they determine it's necessary. By and large they rely on the manufacturer's own risk assessment and whether the manufacturer considers that a low risk, medium risk, high risk.

So if the manufacturer says this is low risk and CMC reviewer at the FDA reviews it and if they also miss it, you know, so, John, it's really a question of they miss it, these guys miss it, yeah, but at the end of the day it's the manufacturer's responsibility.

Q You testified that in your view, the defendant's product shouldn't contain any NDMA or NDEA. Are you aware that nitrosamines have been found in cosmetics?

A Yes, I have been aware.

Q Are you wear that nitrosamines have been found in tobacco and cigarette smoke?

A Yes.

Q Are you aware that nitrosamines have been found in drinking water?

A Yes, I am aware of that.

Q Are you aware that people consume

Page 201

processed foods that include nitrosamines?

A Yes, I am aware of that.

Q Including bacon, sausage and ham?

A Yes, I am aware.

Q Are you aware that beer can contain nitrosamines?

A John, we have to qualify and put me on record as saying the levels of nitrosamines are extremely low in many of these instances. For example, do you know this minimum level that's acceptable to have nitrosamine in water?

Q It's a low level, but it exists, correct?

A It's extremely low level. So nitrosamine, every time you eat bacon, you may get a little bit of nitrosamine. Your body has the ability to detoxify so much. I don't want to get outside of my area but, you know, low levels of nitrosamine and high levels are different stories.

Q Those are the questions I have. Thank you for your time.

A Thank you.

CROSS-EXAMINATION

BY MR. HARKINS:

Q Good evening, Dr. Najafi. Can you

Page 202

hear me okay?
A Yes.
Q My name is Steven Harkins. I represent the Teva defendants and I just have a few followup questions for you here.
You mentioned a few guidances today both for unidentified impurities and then for genotoxic impurities. Do you recall that?
A Yes.
Q Are you aware of ICH, Q3A and Q3B?
A Yes, I am.
Q And those provides guidance on the levels at which any impurity needs to be assessed to the extent it's not in a drug substance, right?
A That's correct.
Q Are you comfortable with the term qualification threshold?
A Yes.
Q And the qualification threshold in ICH, Q3A and Q3B defines the level at which any impurity; harmless, hazardous, needs to be assessed and then analyzed, right?
A Mm-hmm.
Q And unknown impurities that don't meet that threshold strictly under Q3A and Q3B don't get

Page 203

assessed further --
MR. NIGH: Form objection.
Q -- is that correct?
A No, that's not correct. Again, it goes back to -- I didn't catch. You're Steven. Steven, it goes back to looking at the structure -- you know, the changes you're making; looking at the structures that are involved in the chemistry, and you need to anticipate these impurities.
If you are anticipating certain genotoxic impurities, you need to test for it. It could be extremely low levels that doesn't meet the ICH guidelines you are referring to. That's where you end up going to ICH M7. ICH M7 take effect here where they talk about extremely low levels of genotoxic compound. They talk about testing those genotoxic compounds in aims test and various tests and they set limits. And it also -- it's a matter of how -- whether you have an episodic drug or a chronic drug.
For example valsartan, my mom was taking valsartan for ten years. Now she is taking, you know, lisinopril for the last few years. So, you know, it really depends. Once the drug becomes a drug -- I call it life styling drug, then your

Page 204

exposure time -- so you need to consider all of that. And it goes back to the fact that you need to anticipate this impurity and then look for them. Otherwise, you know, you're chromatogram -- you have this valsartan compound is like a huge peak and then there are lots of little peaks and they don't test for it because they are actually below the levels of .1 percent, .2 percent. So they don't test for it and it doesn't require it.
Q Doctor, I promise we will get to where you want to go, but I was just asking specifically under Q3A and Q3B, not subsequent guidelines which we will address in just a minute. If the qualification threshold for an unidentified impurity is not met, then testing further on those unknown impurities is not conducted pursuant to that guideline; is that right?
MR. NIGH: Form objection.
A This is correct with the qualification that I previously state. You need to anticipate based on structures of concern and then test some of those anticipated genotoxic compounds.
Q And you previously testified that the levels for testing of genotoxic or potential genotoxic impurities are far lower?

Page 205

A Far lower, less than .1 part per million, less than 0.1 parts per million, in the case of nitrosamines, zero.
Q And that guidance is at least generally laid out in ICH M7 which you laid out?
A ICH M7.
Q Roughly a thousand full difference between the levels you might be looking at there?
A Yeah.
Q You also testified and you just mentioned again there could be 100 little identified impurities, 100 little unidentified peaks if you ran it over, correct?
A Yes.
Q And even an HPLC test that you used that showed those peaks, that would not be identifying and quantifying each of those impurities just by running a single test with a single set of settings, right?
A You might see 100 little impurities. Those are only UV ultraviolet active compounds. You could also have another 100 that are not ultraviolet active compounds. So now you see that's where, you know, that's where people in need to anticipate certain impurities.

Page 206

Q And to actually assess or quantify any of those, maybe, hundreds of tiny little peaks, you would need specialized testing that was specifically tuned to the impurity that you were looking at and looking for?

A You need to have specialized equipment. That's where we go to CGMP, current good manufacturing practices, which really states that don't use a typewriter to type your letter. Use a computer to type your letter. You see, it's like these manufacturers are still using typewriters in the age of computer and word processor.

We have GCMS which is extremely easy to operate, extremely simple and it comes with a library of molecules stored in it, so all you have to do is just point your cursor to certain impurity and it tells you the molecular weight and it tells you several possible compounds that might be.

Q And you would -- I'm sorry. Are you finished?

A Yes.

Q So you would need a specialized test to identify, for example here, the NDMA or NDEA compound among all of those other little peaks you might see?

Page 207

A I wouldn't call it specialized instrument. These are routine instruments that almost every lab, every university, every company has including, in fact I would hesitate to guess that your clients -- you're representing Teva, right?

Q I am.

A I know for a fact that Teva has probably dozens and dozens of GCMS and LCMS at their facility.

Q And simply running those tests over a drug substance without having them specifically set to the impurity that you are attempting to identify would not allow you to identify and quantify that impurity, correct?

A Repeat your question? I missed it.

Q Running an HPLC or any other test method over an impurity without having that machine specifically set to identify and quantify an impurity that you are trying to identify like in DNA or NDEA would not allow you to identify and quantify that impurity is that correct?

A Running an HPLC would not help you with those impurities that's correct.

Q And, for example, specialized test

Page 208

methods like the ones you used in your work for Valisure later were published eventually that allowed those specific settings to be employed to identify these impurities, correct?

MR. NIGH: Form objection.

A Steven, I would strike the word specialized equipment, because to someone trained in the art, specialized equipment means something that only Lawrence Livermore laboratory has or some cyclotron or something has. These are not specialized equipment, but they need to be thinking about and anticipating NDMA and NDEA and look at it, that's all.

Q You're familiar with the testing methods that were published by the FDA in connection with nitrosamine recalls?

A Yes, I am.

Q Are you aware of those methods having been published anywhere else before they were published by the FDA in connection with the recalls in 2018?

MR. NIGH: Form objection.

A I am not aware, but the methods -- you know, don't need a method. You develop your methods. There are hundreds of methods for testing

Page 209

NDMA if you search the literature. There is a method as early as 1970 for certain testing for NDMA; very validated, very good method.

Q Doctor, imagine my question was specifically with regard to methods for identifying NDMA and NDEA which were published by the FDA in 2018 with respect to the nitrosamine issue. You're familiar with those?

A Yes, I am.

Q And just to clarify, you're not aware of those methods having been published anywhere before that, are you?

MR. NIGH: Form objection.

A I am not aware of FDA publishing method for NDMA. FDA doesn't publish methods to test a lot of drugs. They get involved and, you know, basically somebody when basically something bad happens. A lot of methods that are developed, are developed by industry such as companies like us. We develop the method, we validate the method and then we submit it as part of a CMC package for NDA filing or ANDA filing to the FDA and those methods go into the system.

FDA doesn't really get involved in developing testing. And then ultimately USP gets ahold of those

Page 210

methods and puts it into their, you know, monograph.
Q Doctor, you had never seen those methods published anywhere else before 2018, correct?
MR. NIGH: Form objection.
A I did not see FDA publishing those methods. I am not aware. There might be -- there might have been issued something before. I am not aware, but there are other methods that you can go to besides FDA for nitrosamine analysis.
Q Specifically those methods and I know with respect to FDA you are not aware of anyone else publishing those mods before 2018 are you?
A There are some methods outside of FDA.
Q Dr. Najafi, my question is specific to those methods, just those methods for identified NDMA and NDEA. You have not seen them anywhere else FDA or otherwise before 2018, right?
MR. NIGH: Form objection.
A I answered the question already.
Q I believe you did, but can you please just answer it for me so we have a clear record? You hadn't seen those before 2018?
A I have not seen FDA publishing any methods before prior to 2018, but I may have missed

Page 211

it, but there are other methods on NDMA by other -- by admissions, by industry by other people and there are multiple methods for NDEA analysis.
Q Dr. Najafi, I am not asking about other methods. I am not asking about something that you haven't seen. I am asking you, Dr. Ron Najafi, had never seen any of those methods published anywhere before 2018, correct?
MR. NIGH: Form objection.
A Steven, I think you're trying to get your own, you know, question answered. You can go ahead and answer it.
Q I am not trying to get -- you have not, correct?
MR. NIGH: Form.
A What would you like to hear?
MR. NIGH: Form objection.
Q Whether you had seen those methods published anywhere prior to 2018.
A I mentioned --
MR. NIGH: Form objection.
A -- I have not seen FDA publishing any methods prior to 2018, but I may be wrong, you know. It requires some diligence. There are many other methods that have been published for NDMA analysis

Page 212

by GCMS by other means that are in the literature.
Q Do you think you missed it or that you are wrong?
A Next question, Steven.
MR. NIGH: Well, hold on. Let me do the objection. I am going to say it's asked and answered. I think we asked this question many times and I will continue to warn that he doesn't have anything in his declaration about testing methods and this is really going down the liability path even further.
I would just warn that to the extent he discloses opinions that starts talking about testing methods in the future, I think you all covered this topic.
Q Dr. Najafi, there are other compounds within the nitrosamine class, right?
A Yes.
Q And the nitrosamine class is just one class of potential genotoxic compounds that are addressed by GCMS and other guidelines, correct?
A Yes.
Q Do you know how many classes of compounds or types of covered structure alerts there are?

Page 213

A There are at least five different classes, four or five different classes of compounds by FDA. It's mentioned in the ICH guidelines.
Q And there are other sources that identify potential genotoxic compounds as well, right?
A Yes.
Q And within each of those classes there are numerous individual compounds, right?
A Correct.
Q It's not your testimony that a drug manufacturer is required to perform testing for every type of potential genotoxic compound on every drug substance, is it?
MR. NIGH: Form objection. We're getting way into the liability. At this point I am going to instruct him not to answer, because I think it goes far outside the scope of his opinion.
Q Dr. Najafi, is it your opinion that the reason that these drugs are not equivalent to the reference listed drug is because of the presence of these impurities NDMA and NDEA?
A I believe the fact that they contain these highly DNA active genotoxic impurities, it makes the drug not equivalent and not the same and I

Page 214

think it could have, you know, significant impact on the drug's performance.
Q And correct me if I'm misunderstanding, but I believe it's your testimony that someone looking at the underlying route of synthesis here should have identified the potential for this specific compound and conducted testing for it; is that right?
MR. NIGH: Objection. Scope.
Q I'm sorry. I didn't hear the answer.
THE WITNESS: Should I answer, Daniel?
MR. NIGH: Yeah, you can answer.
A Someone should have anticipated. Once they changed the route of synthesis and given those structural concern the molecules of structural concern, they should have anticipated NDMA and they didn't.
Also, Steven, I want to just to answer your question on methods that are available, there is EPA methods for NDMA testing that goes well before 2018, well before. There are food testing, you know, testing using NDMA for food and they are all using GCMS.
Q I believe you testified actually that someone skilled in the art of chemistry, I think

Page 215

that was your phrase, it would have been obvious to look for this, right?
A Right.
Q FDA had access to information on the valsartan synthesis for all the API manufacturers prior to 2018, correct?
A Yes, correct.
Q And just to confirm your testimony that I believe you gave to Mr. Gisleson just a moment ago, you're not aware of any statements from the FDA prior to June 2018 to the manufacturers of valsartan drug products that they should just test their products for potential presence of nitrosamines, are you?
A I am not aware of FDA stating that they should be aware, but WHO has been on record for stating to all manufacturers of drugs to watch for NDMA. If you have compounds of structures of interest such as sodium nitrite, they need to look for NDMA and just because FDA reviewer missed it doesn't mean the manufacturer should say okay, FDA by and large relies on the manufacturer.
Q The FDA would have had the information for the ZHP product, right?
A Yes.

Page 216

Q They would have had the information for the Mylan product?
MR. NIGH: Object to form. Outside the scope.
Q I believe -- was that a "yes?"
A I assume.
Q Finally, I understand it's your opinion that the level of NDMA or NDEA in the product should be zero, right?
A That's correct.
Q And it's your opinion that any product containing NDMA or NDEA at any level is not the equivalent of RLD and, therefore, be misbranded, adulterated and should be recalled?
MR. NIGH: Form objection. Outside the scope.
A That is my position.
Q Do you recall being shown the Valisure document which indicated that Novartis' valsartan product contained NDMA earlier?
A Yes, I did see that.
Q Assuming that Valisure's data showing levels of NDMA in Novartis' valsartan drug product is correct, it's your opinion that that Novartis drug product containing NDMA would be misbranded,

Page 217

adulterated and should be recalled?
A Assuming that Valisure's testing is correct, which I have no knowledge of whether that testing was correct and I also do not have any knowledge that Novartis is using their old synthesis and they may be using a generic drug manufacturer to make that drug product; assuming that data is correct, it's my opinion that the drug -- that NDMA should not be allowed to be sold; you know, the drug should not be allowed to be sold with NDMA. However, FDA has allowed this interim number, so it hasn't been recalled.
Q But again -- and I understand your qualification, assuming that to be correct and I'm only asking it with regard to the products shown there that did, according to that information contain NDMA, it would be your opinion that that product should be recalled as misbranded and adulterated?
MR. NIGH: Objection. Outside the scope of his opinion.
A So assuming that misbranded, that definition is false and misleading statement, false and misleading statement, right, that's the definition of misbranded drug, and you have

Page 218

carcinogenic impurities, then you have potentially toxic compound that, you know, people don't know about it and that is misleading to whoever is taking the drug.

If I'm taking -- Steven, if I'm taking valsartan and I'm assuming this has zero NDMA in it, if I'm taking torovastatin, Lipitor, okay, I take it every day for, you know, lowering basically cholesterol and various things, I am assuming it's free of any NDMA. It has zero NDMA.

Q And if that product, any product contained any level of NDMA, it would be your opinion that that product is misbranded, adulterated and should be recalled? I am just trying to understand.

A That is my position. That is what I believe the product is not -- it's not being -- we are misleading the public.

Q Thank you, Dr. Najafi. There is no further questions from me.

THE VIDEOGRAPHER: Any other questions from the room?

MR. TRISCHLER: Are there any other questions on behalf of defense counsel?

MR. GISLESON: Not at this time.

Page 219

MR. NIGH: Okay. I would like to take a break. I'd like to come back in 15 minutes.

THE VIDEOGRAPHER: The time is 4:16. This ends Media Unit 5.

(A recess was taken.)

(After the recess the following occurred:)

THE VIDEOGRAPHER: The time is now 4:56. This begins Media 6.

CROSS-EXAMINATION

BY MR. NIGH:

Q Doctor, I'd like to show you a document from Canada and I will represent to you that this was a document that was disclosed as part of your materials considered and given to the defense counsel as well. Now you weren't asked about any of the health Canada testing by any of the defendants, correct?

A That's correct.

Q I want to draw your attention to page 9, if we can scroll down to page 9. Actually let me go to the top first. Let me get to the top here. Here you can see impurities found in certain angiotensin two receptor blocker products also known as sartans, correct?

Page 220

A Correct.

Q And you could see at the top you can see the Canada flag and it says government of Canada; do you see that?

A Absolutely. Yes.

Q And you can also see the words "Health Canada" there is as well. Do you see that?

A I see Health Canada, yes.

Q Okay. Let's go down to page 9.

THE VIDEOGRAPHER: Counsel, while she's jumping to page 9, you didn't announce this is going to be marked as an exhibit.

MR. NIGH: It will be marked as an exhibit.

THE VIDEOGRAPHER: It will be the next one in line.

MR. NIGH: I don't know what we are on, but I don't think we are using anything that has 31, correct?

THE VIDEOGRAPHER: Yes. We have not marked 31 yet.

MR. NIGH: So I'll start at 31. This will be marked as Exhibit 31.

BY MR. NIGH:

Q And Doctor, do you see where it says

Page 221

"Novartis Pharmaceuticals" and right next to it, it shows the word Diovan?

A Yes, I do.

Q And do you see the ones above that refer to valsartan -- Mylan valsartan, Mylan valsartan. Do you see that?

A Yes, I do.

Q Now your understanding is that Diovan is the name brand of valsartan, correct?

A Yes, that's correct.

MR. TRISCHLER: Dan, can I get a standing objection to leading or are you going to do it one time and just ask questions the way they are supposed to be asked?

MR. NIGH: You know, if you want to object to leading, you can. If you want to object to form, you can.

MR. TRISCHLER: I guess I will. Objection to form.

BY MR. NIGH:

Q So you see the name Diovan?

A Yes, I do.

Q Does that refer to name brand valsartan?

A Yes, it does.

Page 222

Q And does Mylan valsartan, does that refer to generic?
MR. TRISCHLER: Objecting to the form and foundation.
Q And Doctor, what is the name brand of valsartan called?
A Diovan.
Q Okay, and next to that, let's scroll back up to the top of this page. Do you see the column that shows NDMA result and nanogram per tablet and NDEA result and nanogram per tablet?
A Yes, I do.
Q Let's scroll down again to November and if we can highlight where it shows not detected.
A Right.
Q Doctor, what does that refer to?
A That refers to no NDMA or NDEA was detected for Diane.
Q So Health Canada detected no NDMA or NDEA for their name brand Diovan?
A Yes, that's correct.
MR. NIGH: We can take this document down. Let's pull up the valsartan petition that was used earlier. I don't actually see an exhibit number in my box.

Page 223

MS. HILTON: That was the question I have, if we actually gave this an exhibit number.
THE VIDEOGRAPHER: That was 28.
MR. TRISCHLER: I was going to say I thought it was 28. Thank you.
BY MR. NIGH:
Q Doctor, my understanding is this Valisure petition was marked 28. Do you recall seeing this petition during your questions?
A Yes, I do.
Q Okay. Let's scroll down to page 9. Now, Dr. Najafi, I believe earlier you said you don't believe Emery Pharma was not disclosed, its name was not disclosed as a part of this report.
A Yes.
Q What does that mean?
A That means that we were not involved in testing any of these drugs that were listed on this petition. Typically if we do get some of these tested and corroborate data, you know, Valisure would have listed us and cited us as being involved in testing.
Q Okay. And here you can see valsartan in Novartis and you can see there are a couple of these show no NDMA detected, correct?

Page 224

A That's correct.
Q Now, it doesn't say Diovan, correct?
A That's correct. There is no reference to Diovan.
Q It says valsartan, correct?
A That's correct.
Q So do you know if this is Novartis name brand medication or Novartis generic drug medication?
A It could be name brand or generic, Novartis generic. I have no idea.
Q Looking at this, you wouldn't be able to tell us?
A No.
Q Okay. And also this petition doesn't test for NDEA in any way in the Novartis pills, correct?
A That's correct. It only tests for NDMA and NDMS.
Q Doctor, let me ask you a couple questions about chemical equivalents. A drug with 20,000 nanograms of NDMA would not be chemically equivalent or the same as a drug with 14 nanograms of NDMA, correct?
MR. TRISCHLER: Objection to job.

Page 225

Q A drug with 10,000 nanograms of NDMA would not be chemically equivalent as a drug with 14 nanograms of NDMA, correct?
MR. TRISCHLER: Object to form.
A No.
Q A drug with 96 nanograms or more of NDMA would not be chemically equivalent as a drug with 14 nanograms of NDMA, correct?
A That's correct.
MR. TRISCHLER: Objection to form.
Q All right. Let's take a look at the next document. Now, Doctor, do you recall defense counsel showing you some -- a document that included a few pages of what's on the USP website?
A Yes, I do.
Q Now the USP website includes a lot more information than what was given in that document, correct?
A That's correct.
Q And you weren't shown this information during defense counsel's questioning from the USP website, correct?
A That's correct.
Q Now, this is the pathway here we can see it's USP/our work/chemical medicines and the

Page 226

title of this document is nitrosamine impurities, correct?
A That's correct.
Q And we can stroll down to the bottom of this page briefly and you can see the URL address, correct?
A Yes. That's correct.
Q Let's go back up. Actually, I want to direct your attention to this paragraph that says companies are responsible for understanding their manufacturing processes which includes identifying and preventing the presence of unacceptable impurities.
This involves developing new predictive approaches along with using suitable methods to detect and control these impurities as well as others that may arise when making changes to manufacturing processes. Did I read that information correctly?
A Yes, you have.
MR. TRISCHLER: Objection to form.
Q Now, Doctor, according to USP, who is responsible for understanding their manufacturing processes?
A Companies are responsible for understanding their manufacturing processes, not USP

Page 227

and not FDA.
Q And those companies, that would be referring to companies that are manufacturing drugs, correct?
A Companies who are manufacturing drugs, in this instance the companies who are manufacturing ARBs.
Q Dr. Najafi, according to USP do they state that in order to detect unacceptable impurities that manufacturers can rely simply on outdated technologies and methods?
MR. TRISCHLER: Object to form.
A I think reading this, this is pretty clear. You want to follow CGMP guideline and CGMP specifically talks about updated equipment, you know, the newest technology and in this instance GCMS or LCMS are not new technologies and basically just as it states, the method needs to be able to detect and control impurities as well as others that may arise when making changes to manufacturing processes, making changes to manufacturing processes. And the word "predictive" is the key where they say the companies need to have a predictive testify involved involving developing new predict testify approach to identifying, you know,

Page 228

impurities such as nitrosamines, the cohorts of interest.
MR. NIGH: You can take this document down.
Q Doctor, do you recall when plaintiff Harkins was asking you questions about whether drugs should be considered adulterated or misbranded?
A Yes, I do.
Q For the purposes of class certification and the declaration that you have offered, are you offering any opinions about whether the defendants' valsartan containing drugs are considered adulterated?
A I am not offering any opinion.
Q For the purposes of class certification and the declaration that you offered, are you offering any opinions about whether the defendants' valsartan-containing drugs are considered misbranded?
A No, I'm not offering any opinion.
Q Okay. I don't have any further questions.
THE VIDEOGRAPHER: Counsel, just real quick you didn't announce it, but the nitrosamine impurities page we were just looking at, is that

Page 229

Exhibit 32?
MR. NIGH: Yes, Exhibit 32. Thank you.
THE VIDEOGRAPHER: Excellent.
MR. TRISCHLER: Nothing from me, Dan, subject to my prior reservations but I'm done.
MR. GISLESON: Nothing further from Aurobindo.
MR HARKINS: Nothing from Teva.
MR. NIGH: Thank you, everybody. Okay. Good night. Thank you.
THE VIDEOGRAPHER: The time is 5:08. That concludes today's deposition.
(Deposition concluded 5:08 p.m.)

CERTIFICATE

I, MICHELLE L. DAWKINS, a Notary Public and Court Reporter of the State of New Jersey, do hereby certify that prior to commencement of the examination, RON NAJAFI was duly sworn remotely by me to testify the truth, the whole truth and nothing but the truth.

I DO FURTHER CERTIFY that the foregoing is a true and accurate transcript of the testimony as taken stenographically by and before me at the time, place and on the date hereinbefore set forth.

I DO FURTHER CERTIFY that I am neither a relative nor employee nor attorney nor counsel of any of the parties to this action, and that I am neither a relative nor employee of such attorney or counsel, and that I am not financially interested in the action.

Michelle L. Dawkins

MICHELLE L. DAWKINS, CCR, RPR
CCR License No. 30XI00224400
RPR ID No. 805591
Notary Public of New Jersey

DANIEL NIGH, ESQ.
dnigh@levinlaw.com

February 14, 2022

RE: In Re: Valsartan, Losartan, Et Al
2/3/2022, Ron Najafi, PhD (#5066624)

The above-referenced transcript is available for review.

Within the applicable timeframe, the witness should read the testimony to verify its accuracy. If there are any changes, the witness should note those with the reason, on the attached Errata Sheet.

The witness should sign the Acknowledgment of Deponent and Errata and return to the deposing attorney. Copies should be sent to all counsel, and to Veritext at erratas-cs@veritext.com

Return completed errata within 30 days from receipt of testimony.

If the witness fails to do so within the time allotted, the transcript may be used as if signed.

Yours,
Veritext Legal Solutions

In Re: Valsartan, Losartan, Et Al
Ron Najafi, PhD (#5066624)

ERRATA SHEET

PAGE_____ LINE_____ CHANGE_____
_____
REASON_____
PAGE_____ LINE_____ CHANGE_____
_____
REASON_____
PAGE_____ LINE_____ CHANGE_____
_____
REASON_____
PAGE_____ LINE_____ CHANGE_____
_____
REASON_____
PAGE_____ LINE_____ CHANGE_____
_____
REASON_____
PAGE_____ LINE_____ CHANGE_____
_____
REASON_____

_____ _____
Ron Najafi, PhD Date

In Re: Valsartan, Losartan, Et Al
Ron Najafi, PhD (#5066624)

ACKNOWLEDGEMENT OF DEPONENT

I, Ron Najafi, PhD, do hereby declare that I have read the foregoing transcript, I have made any corrections, additions, or changes I deemed necessary as noted above to be appended hereto, and that the same is a true, correct and complete transcript of the testimony given by me.

_____ _____
Ron Najafi, PhD Date
*If notary is required

SUBSCRIBED AND SWORN TO BEFORE ME THIS
_____ DAY OF _____, 20___.

_____
NOTARY PUBLIC